

From: Natasha Meertens <[redacted]>
Sent: Thursday, 21 January 2021 4:12 pm
To: Laura Baker <[redacted]>
Subject: Food thickener feedback

Dear Pharmac

The lack of funding of food thickeners stops patients from following SLT advice and puts a lot of patients' lives in danger, due the cost, and the difficulty of finding these products. If they were prescription products and funded this would save lives.

More food/fluid thickeners **should be** funded in the community. Another brand that is good is Instant Thick from Flavour Creations, and it comes in bulk tins or in single serve sachets for easy use.

Funded thickeners **should not be restricted** to those people with "motor neuron disease with swallowing disorder", but should include stroke patients, cancer patients or any patients with dysphagia or swallowing difficulty.

Kind regards

Natasha Meertens | Community Dietitian | Hamilton | Ngaruawahia | Work days; Wednesday, Thursday and Friday only | m [redacted] | p [redacted] | e [redacted]
[redacted] | *Improving health through food and nutrition!*

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From: Nicola Burger (NDHB) <[redacted]>
Sent: Monday, 25 January 2021 9:42 am
To: Consult <Consult@Pharmac.govt.nz>
Cc: Loraine Hamm (NDHB) <[redacted]>; Heather Blackburn (NDHB) <[redacted]>
Subject: Food thickener feedback

To whom it may concern

Food thickeners are used widely by a variety of patients including patients with stroke Parkinson's disease, head and neck cancer and age related swallowing difficulties

The clinical decision to place someone on long term thickened fluids is usually made clinically or with an objective assessment VFSS. Reducing a patients risk of possible life threatening aspiration pneumonias.

These patients need to thicken all of their fluids to remain healthy and as such having the thickener provided by script/special authority would greatly improve the quality of these patients lives and help them remain compliant with our recommendations as the added cost of thickeners can be an added financial burden for many patients.

As such having thickeners funded for all patients with dysphagia would enable our patients to remain healthier for longer

**Nicola Fordham (née Burger) – Speech and Language Therapist
Community Assessment & Rehabilitation Service - Whangarei**

*Rural, Family and Community Health Services
430 4101 ext [redacted] Northland District Health Board
Private Bag 9742/Whangarei 0148 /New Zealand*

[redacted]
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Days of work Community: Tuesday PM, Thursdays and Friday

Mondays and alternate Wednesdays Speech Therapy Department

0800 468758- Speech Therapy Department

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From: Aastha Khatri <[redacted]>
Sent: Tuesday, 26 January 2021 9:52 am
To: Consult <Consult@Pharmac.govt.nz>
Cc: Ma Theresa Araullo <[redacted]>
Subject: Food thickener feedback

Hi

I am sending this email to provide feedback about thickeners.

They are definitely helpful for residents with swallowing difficulties and those at risk of aspiration. Decision of thickening fluids is a clinical decision usually made by nurses, and sometimes an SLT is involved as well.

We use the powder thickeners, however the recent one that we used was not good as it wouldn't properly mix with the liquid and formed pasty lumps.

Hope this feedback is helpful.

Regards

Aastha Khatri Clinical Manager
Bupa Villages & Aged Care NZ

Cornwall Park Hospital, 17 Cornwall Park Ave, Epsom, Auckland, New Zealand, 1003

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From: Amanda Slader-Kearns <[redacted]>

Sent: Tuesday, 26 January 2021 5:17 pm

To: Laura Baker <[redacted]>

Subject: Food thickener feedback

Hi Caitlin,

I just wanted to let you know I have x2 people that I support who have their fluids thickened.

Kind regards

Amanda

Amanda Slader Kearns | Service Manager

IDEA Services

Tel: 022 010 5332 | 06 872 7889 | www.ihc.org.nz

104 Lyndon Road West, Hastings | PO Box 1120, Hastings 4156

[redacted]

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From: Victoria Nadian <[REDACTED]>
Sent: Wednesday, 27 January 2021 10:27 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Food Thickener Feedback

Hi Pharmac,

Please find statement below RE Food thickener feedback.

1. Any evidence which supports the use of food thickeners in the community.
 - Majority of our residents have specialised diet due to their clinical condition's thickeners are used widely in rest homes & hospitals to deliver safe and effective way in providing residents food and fluids, preventing incidence of choking or aspiration & other issues that can be fatal to the persons health. Food thickeners would benefit and vital for the residents who requires food modification, this way they can get the nutrition they need, will still enjoy their food and swallow their food without any difficulty.
 - In some instances when our resident's health decline we have observed that their ability to feed themselves chew or swallow their food deteriorate as well. They have trouble swallowing, can no longer tolerate normal food and fluids as evidence by profuse coughing whilst eating/drinking, low food and fluid intake, decrease in weight and vomiting. In some cases, a resident had a choking episode. After doing thorough assessment and referral to appropriate allied health team, an updated resident care plan has been formulated & implemented. Majority of the residents were prescribed by a dietitian or speech language therapist to be in a food thickener to assist them in swallowing their food. After a while of monitoring and implementing the plan of using food thickeners we were able to resolve the resident's health issues when it comes to their weight, food and fluid intake by using appropriate food modifications.
2. Any evidence that questions, or does not support, the use of food thickeners in the community.
 - As far as I am concerned food thickeners are essential and imperative in delivering safe and effective care to our residents.
3. Any other information you consider relevant for PHARMAC to know to support its future decision making on the funding of food thickeners.
 - As you know dysphagia can affect anyone, however, our elderly is most vulnerable. The ability to eat and drink is fundamental to health & wellbeing. As mentioned above thickeners can avoid occurrence of choking, aspiration, malnutrition and other health concerns that significantly affects a person welfare.

4. In what clinical situation would a person be started on a food thickener?
 - When patient have difficulty tolerating normal food and fluid. Have difficulty chewing food & swallowing. Have incidence of choking and risk for aspiration.
5. Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?
 - Initially staff have to do extensive assessment to determine if the resident needs to be in food thickeners. This is done though trialling other modified food to a resident to see if he/she can tolerate it. E.g. Shifting patient X from normal diet to soft diet and mildly thickened fluid for a trial due to dysphagia, low food and fluid intake with coughing episodes whilst feeding with normal food and fluid.
6. How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)?
 - We have a total of 74 bed capacity. There is a total of 15 residents requiring and benefits from food thickeners (all not funded)
7. Who usually makes the decision to start someone on food thickeners?
 - This is decided by the health team, Nurses to do their assessment, after requiring information and if a resident requires to be on food thickener this is referred to the GP Dietitian or Speech Language Therapist for further assessment and input from them.
8. How is this decision to start someone, for long-term use, on food thickeners made?
 - Once a resident is on a food thickener, this is being reviewed monthly or earlier if needs further modification. A trial of putting back the resident to a normal diet with closely monitoring are done to determine if patient has the ability to swallow or chew her/his food with no difficulty. However, if the health team assessment shows that the resident still have difficulty swallowing and has a high risk of choking and aspiration and the trials has been failed numerous times then the resident would most benefit using food thickener long term.
9. What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?
 - Our main goal in using food thickener is to provide quality of life for our residents. With the use of food thickener due to having difficulty swallowing

they can still enjoy a taste of their food and swallow them with nil issues and not worrying about our residents choking, aspirating and having malnutrition.

10. Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

- It is important that all staff are well informed and trained in preparing food thickeners. There is a big difference when it comes to moderate, mildly and full thickened. Providing unsuitable food thickener to a patient can cause health issues.

11. We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?

- In the past we have been using powdered thickener. As per staff report the powder forms lumps when added to food and drink and does not dissolve well when being mixed. As a result, recommended diet using thickener is not well achieved.
- At present we are using liquid thickener, it is placed in a pump and each pump serves as a measurement to obtain mildly, moderate or full thickened food and fluid. (E.g 1 pump in 100 ml of fluid Moderate thickened, 2 pumps in 100 ml of fluid moderate thickened, 4 pumps in 100 ml of fluid full thickened)

Using this liquid thickener, the staff has been able to provide appropriate thickener to our resident, they also added that the liquid immediately dissolves when being mixed to food or fluid and it only takes seconds to stir them unlike with the powder it takes time and doesn't dissolve well.

I hope the information provided gives enough evidence in funding food thickeners for our dear residents. The residents and the health team will surely benefit from this.

If you require further information, please do not hesitate to contact us.

Thank you.

Kind Regards,
Victoria Nadiasan
Clinical Manager



FORREST HILL

HOME & HOSPITAL

E.

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P.

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From: Linda Goodwin <[redacted]>

Sent: Thursday, 28 January 2021 12:45 pm

To: Consult <Consult@Pharmac.govt.nz>

Subject: Food thickener feedback

Having worked as a Nurse Manager in aged care in New Zealand for 14 + years, and for a variety of providers, I feel that the use of food thickeners is very beneficial for some residents in long term residential aged care facilities. However, I have always insisted on a Speech and Language swallowing assessment prior to the introduction of thickened fluids, and have ensured that the staff have been fully trained in the use of the same.

Without thickened fluids, the resident's chance of aspirating was very high and the extra time taken to ensure their safety with thin fluids often resulted in a degree of dehydration.

Regards

Linda Goodwin

LINDA GOODWIN Clinical Manager

DDI [redacted] | EXT [redacted] | MOB [redacted] | FAX +64 9 238 6979

FRANKLIN OCEANIA HEALTHCARE 44 McNally Road, Pukekohe, 2120

www.oceaniahealthcare.co.nz

From: Ali Shapland <[redacted]>

Sent: Friday, 12 February 2021 6:23 pm

To: Consult <Consult@Pharmac.govt.nz>

Cc: Stephanie Cleave <[redacted]>; James Leigh <[redacted]>; Amanda Slader Kearns <[redacted]>; Ashlee Olsen

<[redacted]>; Bastian Kuesel <[redacted]>; Belinda Barclay

<[redacted]>; Sarah Jane Hodgson <[redacted]>; Tanya Yates

<[redacted]>

Subject: Food/fluid thickener feedback

Hi I am a Service Manager at Idea Services in Hawkes Bay Area

I manage 2 x vocational services (approx. 28 People we support), 2 x very high needs residential houses (5 residents in each house with 24/7 care), and 2 x single occupant flats [redacted].

Of these services, only 4 people we support in one of the very high needs houses have fluid thickeners.

I cant answer all queries, but can answer those I know... in yellow

- In what clinical situation would a person be started on a food thickener? When assessed as necessary by qualified SLT
 - Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia? SLT makes this call
- How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)? 4 out of 40 people under my leadership
 - How many people might have dysphagia and benefit from the use of food thickeners? ?
 - How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners? As above – can only speak for my own guys
- Who usually makes the decision to start someone on food thickeners? Assessment can be done by Manager/staff then recommended to see SLT to clinically assess
 - How is this decision to start someone, for long term use, on food thickeners made? SLT will give us advice and can review at any time we ask or they specify
- How often is the use of food thickeners reviewed? As and when required – when parents ask, when changes occur, when assessment changes, when person has had chest infections or pneumonia
 - How long is someone usually on food thickener(s) for? As long as necessary – people don't usually get better at swallowing – generally declines
 - What evidence/guidance/guidelines are used to support long-term use of food thickeners? SLT decides

- What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life? **prevention of aspiration, nutrition, hydration, quality of life**
 - How much do food thickeners help achieve these goals? **Very well**
- What evidence is available to support this? **All 4 people prescribed these have not aspirated/choked/passed away**
 - Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia? **?**
- Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube? **At one of the vocational services 1 person was tube fed, however is now deceased (death not related to eating/drinking as far as I know)**
 - If so, which people/patient groups? **?**
 - For how long would the use of food thickeners delay the need for a feeding tube? **Not qualified to answer this**
- How is someone's quality of life improved by a food thickener? **Safer and less stressful eating and drinking times – and the fact they stay alive!**
 - How is any improvement in quality of life demonstrated or measured? **?**
 - What evidence is available to support this? **?**
- Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve? **? some people have "Ensure" but this is only very slightly thickened so I wouldn't consider it thickened fluid under this survey**
- We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals? **?**
 - Are there different benefits associated with different types of food thickeners? **?**

I hope this helps to fund thickeners in some small way

Thanks

Ali Shapland

Ali Shapland | Service Manager
IDEA Services

Tel: **Withheld under section 6(2)(b)** | Mobile: **Withheld under section 6(2)(b)** | www.ihc.org.nz
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From: Amy Popman
Sent: Tuesday, 2 February 2021 9:38 AM
To: consult@pharmac.govt.nz <consult@pharmac.govt.nz>
Subject: Funding of food thickeners query

Good morning,

I see that Pharmac is looking into the funding of food thickeners, and has asked specific questions regarding the different types of food thickeners eg liquid vs powder.

I am the dietitian and business manager for Precise - our liquid thickener Precise Thick-N Instant is currently used by 12 DHBs and the majority of aged care groups in New Zealand. We are not Pharmac funded, and I was wondering what the process would be to get Precise funded if the feedback from dietitians and speech therapists was in favour of our liquid thickener

Thanks in advance.

From: Amy Popman <[Withheld under section 9\(2\)\(a\)](#)>
Sent: Wednesday, 17 February 2021 4:13 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Re: Funding of food thickeners query

Hello,

Just following up on my email below regarding funding of food/liquid thickeners

Thanks,

Kind regards,



Amy Popman
Business Manager New Zealand | PRECISE
NZ Registered Dietitian



M: [Withheld under section 9\(2\)\(a\)](#)
Head Office | P: +61 7 3718 5800 | F: +61 7 3271 3807
ADD: 54 Ron Boyle Crescent, Carole Park QLD 4300 Australia.
E: [Withheld under section 9\(2\)\(a\)](#) | www.precisethickn.com.au



- ✓ Low Sodium
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From: Laura Baker <[redacted]>
Sent: Wednesday, 17 February 2021 5:55 PM
To: Amy Popman <[redacted]>
Subject: RE: Funding of food thickeners query

Hi Amy,

At this stage we are seeking information on the use of food thickeners in the community in order to guide future evaluation on what the longer-term funding of food thickeners could be. Based on this we are not currently evaluating new products for listing.

However, if you have information you consider would be helpful with our evaluation such as usage and/or benefit associated with your brand of food thickener (in community based aged care groups), then please feel free to send this through for consideration.

Kind regards,
Laura

Laura Baker | Therapeutic Group Manager

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington

DDI: +64 4 831 3384 | P: +64 4 460 4990 | M: +64 21 959 802 | www.pharmac.govt.nz

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From: Amy Popman <[redacted]>
Sent: Monday, 1 March 2021 4:25 pm
To: Laura Baker <[redacted]>
Subject: Re: Funding of food thickeners query

Hi Laura,

Thanks for getting back to me. It would be of great benefit to community users if Precise was funded

Regarding usage in the community - Precise is used by 238 aged care facilities - most are part of large aged care groups including Arvida, Bupa, Heritage, Oceania, Ryman, Summerset and Ultimate Care, with the remaining being independent facilities. We are also used by ABI Rehab and have some community users in disability care homes.

We are used by 12 DHBs (Northland, Waitemata, Bay of Plenty, Hawkes Bay, Tairāwhiti, Taranaki, Mid Central, Capital & Coast, Nelson/Malborough, West Coast, Canterbury and South Canterbury) Auckland DHB has also approved and will start to use from this month. The majority of patients being discharged from hospital then have to self-fund thickener.

The benefit of Precise over powder thickeners is its accuracy. Precise is compliant to the IDDSI guidelines (compliant at slightly thick, mildly thick, moderately thick and extremely thick) and easier for staff/community users to mix into fluids as it does not cause any lumps. It also thickens within 30 seconds.

I have found when working with powder thickeners they take longer to mix into fluids so often staff add more powder to speed it up - this causes overthickening as well as more waste compared to Precise.

Precise also has a 12-month shelf life on the bottle whether opened or closed - compared to powders which should be disposed of after 30 days of opening. Precise can achieve this extended shelf life due to the hygienic seal - it has 2 one-way valves which prevent the liquid thickener being exposed to the environment

I hope these points are taken into consideration.

Thank you.

Kind regards,



Amy Popman
Business Manager - New Zealand | **PRECISE**
NZ Registered Dietitian



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From: Adele Sullivan <[redacted]>

Sent: Tuesday, 2 March 2021 6:34 pm

To: Consult <Consult@Pharmac.govt.nz>

Subject: Re food thickener

Hi

I am a Nurse Practitioner in neonatal care at Counties Manukau Health.

We now use karicare AR formula for thickened feeds. We don't use it frequently.

We no longer use thickeners.

Adele Sullivan

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From: Lucia Bercinskas <[redacted]>
Sent: Monday, 8 March 2021 7:46 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: 2021 03 PHARMAC Proposal for the funding of food thickeners NZNO response

Kia ora

Please find attached our feedback on the proposal to fund food thickeners

Thank you for the opportunity to participate in this consultation

Ngā mihi

Lucia

Lucia Bercinskas | Senior Policy Analyst

[redacted] | [redacted]

[redacted] | [redacted]

| www.nzno.org.nz

New Zealand Nurses Organisation Tōpūtanga Tapuhi Kaitiaki o Aotearoa | PO Box 2128 | Wellington 6140



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2021/03

8 March 2021

PHARMAC
PO Box 10254
The Terrace
WELLINGTON 6143



By email: consult@pharmac.govt.nz

Tēnā koe

Proposal for funding of food thickeners

Tōpūtanga Tapuhi Kaitiaki o Aotearoa, New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on a proposal for funding of food thickeners.

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand, representing 51,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment matters. NZNO embraces Te Tiriti o Waitangi and contributes to the improvements of the health status and outcomes of all people of Aotearoa New Zealand through influencing health, employment, and social policy development.

Furthermore, we share the intent of the Ministry of Health's definition of equity which equally applies to NZNO work across professional, industrial and member activities.

NZNO supports PHARMAC's consultation to gather information and evidence that supports a decision on the funding of food thickeners in the community. NZNO also acknowledges PHARMAC's decision to retain the funding of food thickeners in hospitals (through Section H of the Pharmaceutical Schedule).

While we are unable to provide detailed comment on the use of food thickeners in the community We do recommend that from an equity perspective, funded food thickeners are made available in the community now and in the future to support improved health outcomes for individuals and their family and whanau

Thank you for the opportunity to contribute to your consultation process.

Nāku noa nā

Lucia Bercinskas
Senior Policy Analyst
Withheld under
section 69(2)(c)

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Wellington 6011
PO Box 2128
Wellington 6140
T 0800 28 38 48
www.nzno.org.nz

From: Katie Ryan <[redacted]>
Sent: Wednesday, 10 March 2021 4:17 pm
To: Laura Baker <[redacted]>; Consult <Consult@Pharmac.govt.nz>
Subject: RE: PHARMAC: Funding of food thickeners – seeking information

Dear Laura,

Thank you for inviting Flavour Creations to submit feedback on the use of thickeners.
Please see attached our written responses to the questions detailed on the web page

If you have any questions, or would like to discuss anything in detail, please do not hesitate to reach out.
Thank you

Best regards,



Katie Ryan (BNutrDiet)
Contracts Coordinator &
Business Development
Manager - WA

T [redacted]
F 07 3373 3099
M [redacted]
E [redacted]

Flavour Creations Pty Ltd
26-32 Murdoch Circuit
Acacia Ridge Qld 4110
flavourcreations.com.au



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| Question | Answer |
|--|---|
| Clinical opinion on the use of food thickeners. | <p>Dysphagia is a medical term used to describe a swallowing difficulty or disorder. As a result of dysphagia people are at increased risk of malnutrition, dehydration, choking and aspiration of foods and fluids.</p> <p>Speech and Language Therapists (SLTs) are responsible for diagnosis and implementing strategies to help patients manage their specific swallowing disorder. The management of dysphagia will also include dietitians, physical therapists, occupational therapists, nurses, carers, feeding assistants, kitchen staff, family, friends and the individual.</p> <p>Compensatory interventions in dysphagia include the use of thickened fluids and texture modified foods, as well as postural adjustments.</p> <p>Food thickeners assist people to swallow fluids more safely. Different levels of thickened fluids are prescribed depending on the severity of dysphagia.</p> <p>Thickened fluids reduce the risk of aspiration.</p> <p>Study by Leder et al. (2013):</p> <ul style="list-style-type: none"> • FEES assessment of 84 patients • Patients aspirated on thin fluids • All 84 patients could swallow Extremely Thick fluids safely, and did not aspirate on Moderately or Mildly Thick fluids • Thickening fluids slows down the flow rate through the mouth and pharynx • Reduces amount of oral/lingual control required to form + keep an intact bolus • Reduces the risk of fluid being misdirected into the airway during swallowing |
| Any evidence which supports the use of food thickeners in the community. | <p>Dysphagia doesn't occur solely with people who are in hospitals or rest homes. Many people within the community require food thickeners to safely consume fluids.</p> <p>Dysphagia can and does cause morbidity and death. Avoidance of dehydration, malnutrition and aspiration pneumonia through the provision of thickened fluids saves significant healthcare costs, hospital admissions and readmissions by preventing the complications that result from untreated dysphagia.</p> |

| | |
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| | <p>Consequences of dysphagia:</p> <ul style="list-style-type: none"> • Malnutrition - As the ability to swallow becomes impaired, adequate dietary intake becomes a challenge and up to 70% of people with dysphagia are malnourished. Malnutrition leads to fatigue, poor skin integrity and eventually organ damage. • Dehydration - As the ability to swallow becomes impaired, adequate fluid intake becomes a challenge, leading to fatigue, confusion, poor skin integrity and eventually organ damage. • Choking - A common sensation experienced by people with dysphagia, swallowed food may stick either in the lower neck or chest. • Aspiration - Food or fluid entering the windpipe of lungs, coughing episodes demonstrate the body attempting to reject fluid. This leads to aspiration pneumonia and/or recurrent chest infections. Penetration of fluid into the airways can introduce bacteria into the lungs, causing pneumonial infection • Silent aspiration - penetration of fluids without cough or other outward signs of difficulty. <p>Dysphagic stroke patients are 3 times more likely to develop pneumonia. Of these, patients with confirmed aspiration are 11 times more likely to develop pneumonia. (Martino et al, 2005).</p> |
| Any evidence that questions, or does not support, the use of food thickeners in the community. | Nil contradictory evidence available |
| Any other information you consider relevant for PHARMAC to know to support its future decision-making on the funding of food thickeners. | <p>Food thickeners are an additional cost for someone to safely live their 'normal' daily life. Ongoing and additional funding of thickeners will assist more people to live a more dignified life.</p> <p>The consequences and medical costs associated with untreated dysphagia are a compelling reason to fund food thickeners. It is far more affordable to prevent the onset of clinical complications that will arise as the result of untreated dysphagia (i.e. dehydration, malnutrition, increased and/or slow to heal wounds, falls, fractures, chest infections, aspiration, pneumonia).</p> |
| In what clinical situation would a person be started on a food thickener? | SLTs are responsible for diagnosis and implementing strategies to help patients manage their specific swallowing disorder. The management of dysphagia will also include dietitians, |

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| <p>Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?</p> | <p>physical therapists, occupational therapists, nurses, carers, feeding assistants, kitchen staff, family, friends and the individual.</p> <p>Compensatory interventions in dysphagia include the use of thickened fluids and texture modified foods as well as postural adjustments.</p> <p>Food thickeners assist people to swallow fluids more safely. Different levels of thickened fluids are prescribed depending on the severity of dysphagia.</p> <p>Dysphagia is a physiological manifestation of many medical conditions. An extensive list of medical conditions are associated with dysphagia, including:</p> <ul style="list-style-type: none"> • Acquired brain injuries (ABI) • Alzheimer's • Amyotrophic Lateral Sclerosis • Cancer (Head, Neck & Throat) • Cerebral Palsy • Chronic Obstructive Pulmonary Disease (COPD) • Dementia • Hepatic Disease (Liver Disease) • Neurological conditions • Huntington's Disease • Lou Gehrig's Disease • Motor Neurone Disease • Multiple Sclerosis • Muscular Dystrophy • Parkinson's disease • Premature babies • Stroke • People born with abnormalities of the swallowing mechanism/hole in the roof of their mouth and lip (cleft palate). <p>Formal Assessment is by Clinical Swallowing Assessment which all SLTs perform on patients with swallowing issues (Mustaffa Kamel, Ward and Cornwell, 2012). This involves assessment of:</p> <ul style="list-style-type: none"> • Orientation, medical state • Oro-motor examination (face, jaw, tongue, cranial nerves involved in swallowing) |
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| | <ul style="list-style-type: none"> • Aspiration risk assessment on different foods and fluids (i.e. different textures or thicknesses) • Diagnosis and treatment decision. <p>Instrumental Assessment can use Video fluoroscopy (Formerly called Modified Barium Swallow (MBS) or Fiberoptic Endoscopic Evaluation of Swallowing (FEES) to confirm clinical swallowing evaluation.</p> |
| <p>How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)?</p> <p>How many people might have dysphagia and benefit from the use of food thickeners?</p> <p>How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners</p> | <p>Instant Thick, food and fluid thickener is currently available for people with dysphagia to purchase within New Zealand and in some instances covered by ACC / Propharma distribution</p> <p>Feedback from SLTs, as well as dietitians, is that more people would benefit from additional availability of thickeners and thickened fluids. Currently the majority of residents in disability homes pay for their required products out of their pensions. Rest home residents are only provided with a limited variety of thickened fluids. Flavour fatigue increases the risk of dehydration.</p> <p>In New Zealand approximately 23% of residents in rest homes are on a modified diet with 10-15% prescribed thickened fluids.</p> <p>Texture-modified diets in aged care facilities: Nutrition, swallow safety and mealtime experience (: Anna Miles¹, Victoria Liang², Julia Sekula², Sharon Bradmore³, Paul Owen², Andrea J Braackhuis² March 2020)¹ Faculty of Science, Speech Science, The University of Auckland, Auckland, New Zealand.² Faculty of Medical and Health Sciences, Discipline of Nutrition, The University of Auckland, Auckland, New Zealand.³ Auckland District Health Board, Auckland, New Zealand.</p> <p>Dysphagia is highly prevalent within inpatient facilities, with estimations showing 15-30% of hospitalised inpatients, 10% to 30% of people over the age of 65 and over 50% of individuals in aged care have swallowing difficulties (Cichero, Heaton & Bassett, 2009 ; Barczi, Sullivan & Robins, 2000 ; Cichero 2012).</p> |
| <p>Who usually makes the decision to start someone on food thickeners?</p> <p>How is this decision to start someone, for long-term use, on food thickeners made?</p> | <p>The SLTs makes this recommendation following thorough clinical assessment. Assessment can include a video fluoroscopy and/or bedside assessment as described above. A part of the decision making process includes consideration of the individual's preference, clinical status and health care preferences.</p> |
| How often is the use of food thickeners reviewed? | This is recommended to occur every 6 months. |

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| <p>How long is someone usually on food thickener(s) for?</p> <p>What evidence/guidance/guidelines are used to support long-term use of food thickeners?</p> | <p>Most of the time dysphagia is a progressive condition, therefore not something which improves over time. An example of where this may differ is for people who develop dysphagia as a result of stroke (depending on the impact and if suitable rehabilitation is available).</p> <p>Long term use of food thickeners support people with ongoing (and typically progressive dysphagia) to allow them to safely consume fluids for the remainder of their life.</p> <p>Situations where short term use of food thickeners are required could be in someone who has acute dysphagia due to illness (e.g. from pneumonia) or a transient period of rehab from stroke.</p> |
| <p>What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?</p> <p>How much do food thickeners help achieve these goals?</p> <p>What evidence is available to support this?</p> <p>Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?</p> | <p>Primarily the use of food/ fluid thickener is designed to support someone swallow their fluids more safely. It is well known that someone with dysphagia is at much higher risk of malnutrition, dehydration and more adverse clinical conditions (e.g. skin tears, increased wounds, infections).</p> <p>Food /fluid thickeners provide someone with the opportunity to consume fluids more safely, therefore improved hydration status - more likely to eat more, etc.</p> |
| <p>Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube?</p> <p>If so, which people/patient groups?</p> | <p>This clinical assessment would be required on a case by case basis by an SLT with contributions from the dietitian and wider medical and care team. Some patient groups could include:</p> <ul style="list-style-type: none"> • Cancer (Head, Neck & Throat) • Cerebral Palsy • Neurological conditions • Huntington's Disease • Lou Gehrig's Disease • Motor Neurone Disease • Multiple Sclerosis • Muscular Dystrophy |

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| For how long would the use of food thickeners delay the need for a feeding tube? | <ul style="list-style-type: none"> Stroke <p>The potential delay would be dependent on the individual, their overall clinical status, including severity of their dysphagia.</p> |
| How is someone's quality of life improved by a food thickener? | Broadly, someone with dysphagia would likely experience coughing and/or choking whilst consuming foods and/or fluids. There are others who experience no immediate symptoms at the time of eating and drinking, but then experience recurrent chest infections or other health complications. Providing thickened fluids to a person with dysphagia provides a better quality of life, reduces the risk of embarrassment, social isolation, etc. |
| How is any improvement in quality of life demonstrated or measured? | Food and fluid thickener can assist someone to consume fluids more safely, therefore lessening their clinical implications and symptoms and improving quality of life. |
| What evidence is available to support this? | |
| Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve? | <p>Extensive research and development underpins all product development at Flavour Creations to ensure our specialist food products are safe and within required parameters. Our products are classified as Foods for Special Medical Purposes. (FSMP).</p> <p>Household ingredients, such as cornflour, are not suitable to use safely for people with dysphagia. These ingredients dilute the nutritional value of the food or drink being thickened, subsequently increasing the onset of dehydration and malnutrition. Furthermore, the poor quality drink they produce is unlikely to be consumed, increasing frailty, falls, fractures, wounds as a result of exacerbating dehydration and malnutrition and poor oral intake.</p> <p>Gum based thickeners should typically be used over starch based thickeners for the following reasons:</p> <ul style="list-style-type: none"> they have been found to demonstrate improved stability in thickness over time (Garcia, 2005; Matta et al 2006); the risk of clumping is reduced compared to starch based thickeners (Garcia, 2005); starch based thickeners may have reduced palatability and add a starchy flavour and grainy texture (Cichero, 2010; Matta, 2006) |

We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?

Are there different benefits associated with different types of food thickeners?

Flavour Creations prides itself on manufacturing innovative solutions that are not only safe for consumers, but are also cost effective.

Instant Thick is now available in a powder and liquid format offering the consumer greater dignity and choice based on their preferences. Both are based on xanthan gum (we do not use guar gum) resulting in drinks of brilliant clarity with no impact on taste or smell. Xanthan gum also ensures that no sticky residue is left behind in the individual's mouth. Our one measure per serve solutions minimise risks when mixing thickened fluids. (Other options on the market require consumers to count up to 8 for one serve of drink.)

A drink that is easier to make, nicer to drink with no offensive appearance, smell or taste, and made from Xanthan gum is much easier to swallow.

released under the
Official Information Act

From: Hannah Barnes <[redacted]>
Sent: Thursday, 11 March 2021 1:36 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Funding of food thickeners Spectrum Care

Kia ora,

I would like to make a submission regarding the funding of food thickener. Please see attached letter with details of the use of food thickener at Spectrum Care.

Thank you for your consideration,

Ngā mihi,
Hannah Barnes

Hannah Barnes
Practice Lead, Speech-Language Therapy
DDI: [redacted] **M:** [redacted]



Level 2, 205 Great South Rd, Greenlane, Auckland 1051
PO Box 74422, Greenlane, Auckland 1546
Ph: 09 634 3790
spectrumcare.org.nz

Make a Referral
[to our specialist support teams](#)

Every person with a disability deserves a life of choice, freedom and independence



Do the right thing.

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11 March 2021

To whom it may concern,

I am writing to submit feedback on the possible funding of food thickeners. My role is the Practice Lead of the Speech language Therapy (SLT) Team at Spectrum Care – a disability support provider. Spectrum Care provides a range of support services, including supported living for adults with developmental and intellectual disabilities. This submission is based primarily on current practice and experience, and is in support of funding fluid thickener.

The SLT team at Spectrum Care assess risks around swallowing, implement swallowing strategies and diet modifications where appropriate for people in supported living. The SLT team are not a funded service, most adults with disabilities can access DHB services only. Dysphagia and swallowing difficulties are highly prevalent in the population of adults with disabilities (Hedworth et al 2019; Manduchi et al 2019).

At Spectrum Care, of the 460 people currently in supported living who have a combination of intellectual and physical disabilities:

- 61% have identified risks around their eating and drinking
- 28% require some form of modified diet
- 14% are considered high risk due to the number of risks identified around their eating and drinking
- 8% require a puree diet
- 6% (29) require thickened fluids

With an aging population, it can be expected the number of people requiring fluid thickener will increase, given swallowing abilities tend to deteriorate with age.

The cost to individuals who require thickener is significant. Adults with disabilities often have very limited finances due to low benefits and limited opportunities for employment or further income. Typically, people may have \$60-\$70 per week to cover activities, personal items, some medical costs and general costs. With no funding available the cost of thickener impacts people's ability to use their limited funds for things that help improve their quality of life or work towards long term goals.

Price varies depending on the brand of thickener and supplier. Spectrum Care has negotiated discounted rates with both the Flavour Creations supplier, and the pharmacy which stock and deliver product. For people in the community not supported by Spectrum Care, costs are increased, and they may have to pay additional in shipping costs.

Costs have been calculated based on recommended 7-8 drinks per person per day, of Flavour Creations Easy Thick Rapid 600g tin – this is the cheapest thickener option available. These calculations do not take into account any potential spillage, people who drink more than 8 serves per day, or any errors in measurement which may lead to increased use of thickener and increased cost. In addition, the current supplier of thickener Flavour Creations Easy Thick Rapid will be changing their product during 2021, and have advised costs will be increasing. Costings below should therefore be taken as a minimum.

Of the 29 people currently on thickened fluids, this table indicates minimum cost to an individual per week and per month.

| | Number of people | Cost per week | Cost per month |
|------------------|------------------|---------------|----------------|
| Mildly thick | 21 | \$10.92 | \$43.68 |
| Moderately thick | 8 | \$20.69 | \$82.76 |

1 In what clinical situation would a person be started on a food thickener? Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

For people accessing Spectrum Care services, a person would be started on thickener following an individualised swallowing assessment from SLT (either Spectrum Care SLT, or DHB SLT). Assessments are indicated through proactive screening of dysphagia risks, incidents such as chest infections, or support staff/whanau raising concerns or changes about a person's eating, drinking and swallowing.

SLT swallowing assessment can help to indicate what stage of a swallow a person is having difficulty with, and if they are suspected to be aspirating. Various strategies are trialled such as pacing, and adaptive cups before trialling thickened fluids. If assessment indicates thickened fluids may compensate for person's swallowing difficulties, they will be trialled for a period 1-2 weeks before an SLT gives the recommendation. Where possible, a referral to DHB to complete an instrumental assessment such as video fluoroscopy study is made, as this can show more objectively if thickened fluids are appropriate strategy to compensate for swallowing difficulties. However, referrals are typically only accepted when a person has a history of chest infections, and instrumental assessment is not suitable for all people (e.g. people who move around, would have difficulty following instructions in unfamiliar environment, person becomes distressed in hospital environment etc.), so instrumental assessment is not always possible.

Although individualised assessment is necessary, general indicators which may suggest thickened fluids could be appropriate can include: difficulty controlling thin fluids, delayed initiation of swallow, signs of aspiration such as wet sounding voice, coughing, difficulty catching breath and history of chest infections. For people who also show significant signs of aspiration and difficulty on food or puree, thickening fluids may not be a suitable management strategy. Where people are managing food easier than fluids, then thickened fluids may be suitable. Consideration is also given to the individual preference and choice. Some people may be able to communicate if they wish to try thickened fluids or accept risk on thin fluids, others may need family/whanau input, others may indicate will and preference by how much they drink e.g. for some who frequently refuse thickened drinks it is discontinued.

When a person is recommended thickened fluids, some training on importance of oral hygiene is also given, due to the ongoing risk of aspiration on saliva, and substantial evidence around good oral health reducing frequency and severity of chest infections.

2 How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)? How many people might have dysphagia and benefit from the use of food thickeners? How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners?

As per numbers above, 6% of people (29 people) use fluid thickener, at significant cost to the individual

3 Who usually makes the decision to start someone on food thickeners? How is this decision to start someone, for long-term use, on food thickeners made?

Speech language therapist recommendation following individualised swallowing assessment, often with consultation with the person, whanau, and medical team/GP where appropriate.

4. How often is the use of food thickeners reviewed? How long is someone usually on food thickener(s) for? What evidence/guidance/guidelines are used to support long term use of food thickeners?

Spectrum Care has a review process where each person on a modified diet has their diet reviewed by an SLT every 1 or 2 years (depending on risk level). Each time a person has a chest infection their diet is also reviewed to ensure it is still appropriate and meeting person's needs. Where people are admitted to hospital they may be seen for another SLT assessment by in patient DHB SLTs.

Though there is limited evidence about ongoing use of thickener particularly for adults with disabilities (Manduchi, Fainman, Walshe, 2019), we follow position statements, guidance and recommendations from professional bodies including NZ Speech language Therapists' Association, Speech Pathology Australia, and American Speech language Hearing Association.

5. What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life? How much do food thickeners help achieve these goals? What evidence is available to support this? Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

The primary goal for most people is to reduce risk of aspiration and chest infections secondary to aspiration. It is difficult to collect objective evidence on whether this is achieved, as it is not known what chest infections a person would have had if they were not on thickened fluids. However in our experience there has been a decrease in instances of aspiration pneumonia for some people. There are multiple cases where a person was getting regular chest infections, and following change to thickened fluids, no longer gets chest infections. Where possible, video fluoroscopy can give more objective information if thickened fluids reduce aspiration, but as described above these can be difficult to access.

Another goal can be to reduce dehydration – for some people who spill excessive amounts of fluid, it can be difficult to retain enough fluid for them to stay sufficiently hydrated. When fluids are thickened, for some people there is significantly less spillage and it is easier for people to swallow enough to stay adequately hydrated.

Quality of life is also a significant consideration – for people who cough, gag, and splutter on even small amounts of thin fluids, having thickened fluids can lead to significantly improved enjoyment of mealtimes.

Clinical risk – there is some evidence to suggest where people are aspirating on thickened fluids, instances of aspiration pneumonia may be longer and more severe, and thickened fluids can be more difficult to cough up. To manage this risk, where a person on thickened fluids continues to have chest infections their diet is reviewed, and consideration given to whether an alternative strategy such as returning to thin fluids, or having water only may be appropriate for the person.

6. Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube? If so, which people/patient groups? For how long would the use of food thickeners delay the need for a feeding tube?

The decision to get a feeding tube or not can be complicated and ongoing. We do not have evidence to say with any certainty if there are people who would have opted to get a feeding tube, however in my professional opinion with experience in supporting people with very severe dysphagia who are at high risk of aspiration, dehydration and malnutrition, I do believe access to thickened fluids can result in the person and their family/whanau, and medical team choosing to continue with oral feeding rather than tube feeding. Having the option of thickened fluids increases the options that are available to a person in managing dysphagia

7. How is someone's quality of life improved by a food thickener? How is any improvement in quality of life demonstrated or measured? What evidence is available to support this?

Access to thickened fluids can help ensure a person enjoy a range of drinks (such as tea, coffee, juice etc) where if they were on thin fluids only, they may be recommended free water protocol, with no access to preferred drinks.

As above – for people who cough, gag, and splutter on thin fluids, having thickened fluids can lead to significantly improved enjoyment of mealtimes

8. Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve?

Not that I am aware of. We have previously come across people using Bakels Colset – a starch based thickener designed for baking, NOT thickening fluids. This product did not meet needs as it continued to thicken over time, added significant calories to drinks and became a thin liquid when in contact with saliva. This was being used as it was thought to be a cheaper alternative, but did not meet the needs.

9 We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals? Are there different benefits associated with different types of food thickeners?

There can be some benefits to making foods naturally thicker by adding banana, custard etc to the food, however this is inconsistent and difficult to measure the thickness to comply with IDDSI standards. This also changes the calories in a drink which may be beneficial for a person, but in other instances can impact on appetite and reduce willingness to eat meals.

In conclusion, thickened fluids are an important clinical option which can provide significant value in improving quality of life and reducing risk of aspiration pneumonia for some individuals with severe dysphagia. If you would like further information, I would be happy meet or answer further questions.

Sincerely,
Hannah Barnes
Practice Lead Speech-Language Therapy, Spectrum Care

Withheld under

Withheld under section 9(2)(a)

205 Great South Road

References

Hedworth, K , Miles, A , Hausman, A , & Roker, J (2019) An investigation of nutrition and swallowing risk factors in a New Zealand population of persons with intellectual disability. *Speech, Language and Hearing*. 22(4), 204-214.

Manduchi, B , Fainman, G & Walshe, M (2019) Interventions for Feeding and Swallowing Disorders in Adults with Intellectual Disability: A Systematic Review of the Evidence *Dysphagia*. <https://doi.org/10.1007/s00455-019-10038-5>

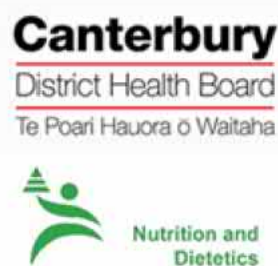
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From: Emily Gilchrist <[REDACTED]>
Sent: Thursday, 11 March 2021 3:12 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Food thickener feedback

Hi there

Please see attached feedback around funding of food thickeners from a dietitian perspective.

Many thanks
Emily



Emily Gilchrist | Dietitian Team Leader and Clinical Dietitian
Nutrition & Dietetics | Christchurch Hospital
2 Riccarton Avenue, Private Bag 4711 Christchurch 8120, New Zealand

t: [REDACTED] | e: [REDACTED]

 please don't print this e-mail unless you really need to

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What type of feedback is PHARMAC looking for?

- clinical opinion on the use of food thickeners.

Essential for the quality of life for those living with dysphagia. This is not exclusive to motor neuron disease. It may include those with head and neck cancer following surgery or radiation treatment with impaired swallowing functions. Typically, these patients also need nutritional supplements as they have increased nutritional requirements, and these oral nutritional supplements need to be thickened.

Other groups may include: stroke patients, neurosurgical patients with traumatic brain injuries (TBI)

Patients I see enjoy being able to thicken their favourite beverage such as lemonade or ginger ale or even the odd serving of alcohol and have choice between fluids rather than relying on pre-thickened fluids they don't often enjoy in hospital. It is also very disappointing when patients discharge from hospital and we provide recommendations that are costly, and we are unable to provide options such as funded or partially funded thickeners. We cannot expect people to adhere to recommendations when they have to source their own thickeners and pay for them.

- In what clinical situation would a person be started on a food thickener?

After an instrumental swallow assessment done by a speech and language therapist who has seen aspiration of thin fluids or functional decline in swallow which by default makes having thin fluids difficult to swallow properly

- Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

From a dietitian perspective I would suggest anyone who is unlikely to improve with swallow rehab/intensive speech and language therapist input and has a long-term dysphagia. People with dysphagia which is sudden onset and may improve in a timely manner with swallow rehab may rely less on thickeners and therefore not benefit as much, however this same group may also benefit from them more as they are typically 'well' and it is important to keep them out of hospital.

- Who usually makes the decision to start someone on food thickeners?

Speech and language therapists.

- How is this decision to start someone, for long term use, on food thickeners made?

It is a patient and health professional decision. A patient may decide to 'accept the risk' of not using food thickeners and not follow recommendations, this is often what we see in patient who may not have long to live and the risk outweighs the benefit. It is a very different situation for those who are otherwise fit and well but have a swallowing issue.

- How long is someone usually on food thickener(s) for?

It depends on their swallow function, ongoing swallow assessments and what is best for the patient. If a patient is nearing end of life, then they may choose to not use thickeners knowing and accepting the risk.

- What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?

All of the above

- Quality of life

- Hydration if no other forms are given (IVFs or enteral feeding)

- To maintain adequate nutrition if patient is requiring an oral nutritional supplement orally and is unable to have these via a feeding tube. They would require them to be thickened as they are classed as a thin fluid

- To prevent aspiration pneumonia and complications from this such as recurrent hospital admissions and mortality

- Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

Yes, if they are not thickened correctly.

- Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube?

Yes. Some independent patients who can enjoy thickened oral nutritional supplements orally while they are thickened may be able to maintain adequate nutrition orally and therefore not need a feeding tube. It may also allow them to create their own high energy high protein fluids that are considered a 'safe' consistency

- If so, which people/patient groups?

Head and neck cancer patients, Stroke, neurosurgery/neurology patients

- For how long would the use of food thickeners delay the need for a feeding tube?

This could be indefinitely if patients were able to continue drinking thickened liquids and therefore meet their nutritional requirements. However, this would depend on the person and diagnosis, if it was a diagnosis that would worsen over time the use of thickened fluids may not be appropriate as swallow impairment progressed and got worse or the patient was unable to swallow at all then food thickeners will not impact the need for a feeding tube insertion at all.

- How is someone's quality of life improved by a food thickener?

Patients can consume 'normal' fluids with friends and family when a thickener is added. Thickener can be added to hot, cold and carbonated beverages and patients often get a huge sense of enjoyment from consuming their favourite beverages.

- How is any improvement in quality of life demonstrated or measured?

QOL can be measured based on patient experience, feedback and satisfaction, however this is not measured routinely.

I can comment on my experiences and if a patient was to be given a choice between being nil by mouth (nothing via mouth) versus able to have some thickened fluids orally they would much rather have thickened fluids and be able to taste flavours that are known and familiar and bring a sense of enjoyment and normality.

- Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve?

Other than ready to drink pre-thickened drinks that are unfunded there is nothing that compares. The pre-thickened beverages are limited in flavours and patients often find them too sweet or unenjoyable.

- We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?

A liquid thickener is far more practical and easier to use and mix, also these tend to be more stable when it comes to adding to hot and cold beverages or even freezing drinks/foods. Most liquid thickeners also have a pump that delivers the appropriate amount per serve, this lessens human error and results in a more accurate consistency.

- Are there different benefits associated with different types of food thickeners?
As above

Thickened fluids statement – Acute Stroke Dietitian

Many patients I see require thickened fluids post stroke due to ongoing dysphagia. Often, they go home requiring thickened fluids/food. Reducing the barriers to achieving safe food/fluid intake at home is very important and I think funding food thickeners, thereby making them more accessible, would go a long way in achieving this.

Funding the use of food thickeners for patient would encourage patients to use food thickeners at home, reducing their risk of aspiration or unpleasant food/drink experiences e.g. coughing and choking. This would also result in increased food and fluid intake which is very important as patients on modified texture diets have been shown to have reduced energy/protein intake. Greater accessibility of food thickeners would increase the patient's food and fluid choices and as a result improve food/fluid enjoyment and QoL.

From: Tessa Starr <[redacted]>

Sent: Thursday, 11 March 2021 4:16 pm

To: Consult <Consult@Pharmac.govt.nz>

Subject: Funding of food thickeners feedback

Hi there

Please see our feedback on the funding of food thickeners attached.

Thank you

Tessa Starr
Speech Language Therapist
Christchurch Hospital

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- In what clinical situation would a person be started on a food thickener?

When a person's swallow is assessed by a speech language therapist, they are usually trialled with several different food and fluid textures. If the thicker fluids appear safer (i.e. less likely to be aspirated into the lungs) than the thinner ones and their use is clinically indicated, then a food/fluid thickener may be recommended

- Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

No, not based on etiology or severity. Although dysphagia is more common in certain medical conditions, its presence and severity cannot be generalised in this way. In general, the more severe the dysphagia, the more likely the person is to require texture-modified food and fluid which may require the use of food/fluid thickener. However, there are some people with severe dysphagia who are able to safely drink fluids without use of a thickener. The need for food/fluid thickener is best determined by instrumental assessment with SLT, as described below

- Who usually makes the decision to start someone on food thickeners?

In the hospital, this decision is usually made by the speech language therapist. Occasionally, it is made by a registered nurse or a doctor.

- How is this decision to start someone, for long-term use, on food thickeners made?

For a speech language therapist (SLT) at Christchurch Hospital, this decision is usually made following a thorough swallow assessment, usually an instrumental swallow assessment such as Videofluoroscopic Swallowing Study (VFSS) or Flexible Endoscopic Evaluation of Swallowing (FEES). Videos of these assessments are reviewed by more than one SLT. If the recommendation for thickener is long-term, the person, their family and their doctor are also often involved in this decision

- How often is the use of food thickeners reviewed?

For the SLTs at Christchurch Hospital, use of thickener is reviewed as often as daily and use of thickener is stopped as soon as it is safe to do so or no longer clinically indicated. Sometimes it may be reviewed every 1-2 weeks if the person requires VFSS or FEES which is not provided daily. Once the person enters the community, use is reviewed less often.

- How long is someone usually on food thickener(s) for?

Sometimes one day. Sometimes for life.

- What evidence/guidance/guidelines are used to support long-term use of food thickeners?

SLT's clinical judgement and evidence-based practice

- What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?

Primarily prevention of aspiration, however it can play an important role in quality of life for some people. The use of food/fluid thickeners can reduce discomfort, distress, and embarrassment associated with eating and drinking, and can facilitate social participation and enjoyment of food and drinks.

- How much do food thickeners help achieve these goals?

Food/fluid thickeners can sometimes be the only factor allowing these goals to be achieved, particularly in the case of airway protection. In other cases, they are an important part of clinical recommendations, which are always made to best support each individual.

- What evidence is available to support this?

As above.

- Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

The presence of dysphagia symptoms does not automatically mean food/fluid thickeners are required or even safe. Thickened fluids are more likely to be silently aspirated than thin fluids, meaning that their use when not recommended could pose a risk equal to that of not using them where needed. Because of this an SLT's recommendation for the use of thickener is made carefully, and preferably following instrumental assessment.

Additionally, thickened fluids can reduce absorption of medications which have been dispersed in them and can contribute to dehydration

- Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube?

I imagine that if a person was unable to eat and drink without thickener and was unable to access thickener then they may require a feeding tube.

- If so, which people/patient groups?

Presence and severity of dysphagia cannot be generalised

- For how long would the use of food thickeners delay the need for a feeding tube?

Depends on the person. In the situation described above, this could delay it permanently.

- How is someone's quality of life improved by a food thickener?

As mentioned earlier, some people do find it more comfortable and enjoyable to have the thickener (for example, if normal fluids are causing distressing/embarrassing coughing episodes.) Quality of life is also improved by preventing aspiration pneumonia (and therefore potential hospital admission)

- Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve?

No

- We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?

Yes They all thicken fluids

- Are there different benefits associated with different types of food thickeners?

Yes. Anecdotally, SLTs, nursing staff and patients have found Precise liquid thickener easier to use than powder and with a more desirable result (less lumpy).

Accessibility in terms of packaging can facilitate independence with preparation in those patients who have physical limitations. (For example, some people may find it easier to use the pump bottle offered with Precise liquid thickener than the fine motor movements of opening a can of powder, measuring/spooning it out)

Precise liquid thickener also develops viscosity within 30 seconds which is then stable for 24 hours whereas powdered thickener continues to thicken over time

Precise is freezeable, and has a neutral flavour whereas powdered thickeners alter the taste of drinks.

Additionally, Precise is halal, kosher, Vegan, Gluten Free, Lactose Free, Nut Free and suitable for diabetics.

Feedback provided by Tessa Starr, Bron Hunter, Wendy Fletcher, Astra Robinson-Millen and Sachi Summerlee on behalf of the Christchurch Hospital adult speech language therapists

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Official Information Act

From: Rae Taylor <[redacted]>
Sent: Thursday, 11 March 2021 7:46 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Funding of Food Thickeners SLT Submission

Hi,

Attached is my Speech Language Therapy submission regarding the funding of Food Thickeners. I hope it reads OK. Sorry, I have been a bit rushed in writing this as only found it in my email a couple of days ago!

Please don't hesitate to contact me if you have any questions.

Kind regards,

Rae

Rae Taylor
Speech Language Therapist

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Rachel (Rae) Taylor
29 Elm Grove, Avonside, Christchurch 8011, New Zealand
Phone: [redacted]

Funding of Fluid Thickeners

Background

I am a Speech and Language Therapist working for Therapy Professionals, a private multidisciplinary practice in Christchurch. At Therapy Professionals we have a contract through the Ministry of Health to work with people that were living in the Templeton Centre which housed people with multiple disabilities. This centre closed in 1997 and residents were moved into group homes in the community receiving 24 hour care.

There are currently 221 people with intellectual disabilities on the Templeton Contract. A big component of my job is to assess people with dysphagia on this contract. All of the people living in these group homes are living on government benefits, have low incomes and are very vulnerable. The majority of them have communication difficulties and are unable to advocate for their needs.

Evidence and information on the use of food thickeners:

I would recommend using fluid thickener if the person with intellectual disabilities was frequently coughing when drinking. The person may have been experiencing recurrent chest infections. They may have difficulty controlling the rate of flow of the fluid when drinking. Reports from carers would help to inform my decision making. I have noticed that the more physically disabled the person is, their dysphagia severity increases and these people often have difficulty coordinating the pharyngeal phase of their swallow.

Currently there are 31 people (out of 221) on my caseload who are using fluid thickener. 6 of these people are having their drinks thickened to Extremely Thick (level 4), 5 to Moderately Thick (level 3), 21 to Mildly Thick (level 2) and 4 to Slightly Thick (level 1). The clients who are having their drinks thickened to Extremely Thick are fed by their carers, have severe dysphagia and are severely physically and intellectually disabled.

The people on The Templeton Contract are an ageing group of people who are requiring more assistance over time and are at risk of developing other conditions such as: Dementia, Parkinson's Disease, CVA. It is predicted that the number of people needing fluid thickener will increase as they age. There are a number of people with Down's Syndrome that are a high risk of developing Dementia and associated dysphagia as they age.

The decision to start someone on food thickener is always made by a Speech Language Therapist at Therapy Professionals. This is made following assessment of the person's eating and drinking. Different fluid consistencies are trialled during the assessment process starting with the thinnest consistency. The recommended consistency of fluid thickener is usually trialled for 2 weeks to determine whether this improves the person's ability to drink without coughing. The majority of people on the Templeton Contract with severe disabilities are on thickened fluids for their whole life time. The use of fluid thickeners is generally reviewed every 6-12 months as needed. A carer or Health Advisor may request a review of a person's eating and drinking.

Funding of Fluid Thickeners

following hospital admission for aspiration pneumonia or they may report that the person is having increased coughing with their current level of fluid thickener

The goals of therapy when using fluid thickeners are to prevent aspiration pneumonia, help the person get adequate nutrition and improve their quality of life. For some people having their drinks thickened can enable them to drink independently as thickening their drinks can help them control the rate of fluid. Some of the clients I support require assistance with spoon feeding because of their physical disability but they are able to independently feed themselves a drink if it is thickened to level 1-3. This improves their quality of life and reduces their risk of aspiration pneumonia.

Some of the Templeton Clients whose drinks are thickened to moderately or extremely thick would most likely have to be fed by a feeding tube if their drinks were not thickened. These clients are at higher risk of aspiration pneumonia as they are more physically disabled and their immune systems are often compromised.

A person's quality of life is improved by fluid thickener as they are less likely to have frequent hospital admissions for aspiration pneumonia. They can continue to enjoy the social aspect of eating and drinking with their friends and family rather than being tube fed.

Most of the clients I support use a powder thickener such as Nutilis. This can be difficult to mix as it is quite lumpy and keeps thickening over time. There is a tendency of carers to give drinks that are thicker than the recommended consistency using Nutilis. Some of the NZ Care houses have started to use Ezi Thick rapid which carers have reported stabilises to its consistency more quickly. I have been recommending clients try Precise Thick-N Liquid Thickener as this thickens more quickly, holds its consistency over time and the consistency is more accurate than the powder thickeners.

There appear to be inconsistencies around clients who are funded for their thickener and clients having to fund their own thickener. As this is something they need in order to drink safely, reduce their risk of aspirating, I feel strongly that they should all be funded for food and fluid thickeners.

Please feel free to contact me if you require further information.

Rae Taylor
Speech Language Therapist
Therapy Professionals
Phone: Withheld under

From: Adele Siave <[redacted]>
Sent: Friday, 12 March 2021 11:38 am
To: Consult <Consult@Pharmac.govt.nz>
Subject: Submission on food fluid thickeners

Kia ora,

Please find attached 2 submissions regarding fluid thickeners.
One is from the national SLT health leaders forum and the other is from Loraine Hamm, SLT at Northland DHB, which is specifically regarding Paediatrics.

Warm regards,
Adele

Adele Siave

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Canterbury
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Te Poari Hauora Ō Waitaha

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Submission to Pharmac

Subject: Funding of food/fluid thickeners seeking information

Submitted by the National Speech Language Therapy (SLT) Health Leaders Group, representing all SLT services within DHBs in New Zealand.

The National SLT Health Leaders Group supports the funding of thickeners, where the recommendation for thickening fluids is made by a SLT, within well defined parameters, e.g. following an objective assessment of swallowing, reviews within certain time periods.

Please find below further detailed information in response to the questions posed for this submission

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| 1. | In what clinical situation would a person be started on a fluid thickener? |
| | Most commonly thickener is used to thicken liquids in order to slow down the transit of regular thin liquids for a person with dysphagia. Thickened fluids are typically used in situations where there is either an oral weakness and limited control over a bolus entering the pharynx so pre swallow airway closure is compromised (this could be neurological origin such as stroke/Parkinson's disease/cerebral palsy/Guillain Barre; neuromuscular such as myasthenia gravis or motor impairment due to head and neck surgery) where there is a delayed initiation of the pharyngeal swallow response (typically neurological origin), or where reduced airway closure to protect the airway is noted (either neurological or as a result of head and neck/ thyroid/cardiac surgery where the recurrent laryngeal nerve may have suffered injury). |
| 1a. | Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a fluid thickener? Is this based on severity of dysphagia? |
| | This is assessed on an individual basis, usually following an objective instrumental assessment of swallowing to determine biomechanics and safety of swallowing, identify the most appropriate compensatory strategies (including thickened fluids) and to plan potential rehabilitative exercises for the person. It is not necessarily based on severity of dysphagia but there can be a correlation. It is based on a combination of physiological deficit, symptom presentation, prediction of risk of secondary complications (i.e. pneumonia) immediate resolution of discomfort and longer term quality of life. Goals of care should be determined by patient choice. |
| 2. | How many people are currently using fluid thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)? |
| | This would be very difficult to identify within a district. There would be patients on the SLT active caseload, those discharged with chronic dysphagia who may use it long term and those who are not. |

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| | <p>known to SLT who reside in residential care facilities. A number of those with chronic dysphagia that are known to SLT are self funding thickener because they are not necessarily MND patients.</p> <p>If prescription of thickener was more regulated, we anticipate that fewer patients would be on it - as nursing staff in care facilities will not be able to provide thickened fluids without an appropriate swallow evaluation. However, we may also see a small increase from those that do not use thickener currently due to prohibitive costs and access to thickener, but in doing so are risking their health and potentially costing the health system in admissions to hospital/reliance on tube feeding.</p> |
| 2a. | How many people might have dysphagia and benefit from the use of fluid thickeners? |
| | <p>The numbers of patients presenting with dysphagia is already reported in the literature (depends on whether you look at the acute stroke population or those over 70 or those with a diagnosis of Parkinson's etc)</p> <p>It is difficult to determine numbers of people with dysphagia that might benefit from the use of thickeners. This depends on a number of individual factors and is outlined further throughout this document A rough calculation by one DHB calculated that 10% of inpatients with dysphagia were recommended thickened fluids by SLT on discharge home</p> |
| 2b | How many people currently living in care facilities (e g rest homes) have dysphagia that might benefit from the use of fluid thickeners? |
| | <p>We do not have data on these numbers within districts, however we suspect that the number with dysphagia and those that may benefit from food/fluid thickener are greater numbers than we might expect.</p> <p>The following articles indicate some estimated numbers</p> <p>The prevalence of dysphagia in care facilities is higher than in populations living in the community. In people over 65 years of age living in the community, dysphagia prevalence is 14-33% ((Chen, Golub, Hapner, & Johns III, 2009; Kawashima, Motohashi, & Fujishima, 2004; Roy, Stemple, Merrill, & Thomas, 2007). In aged care facilities, prevalence is 9-70% (Bomfim, Chiari, & Roque, 2013; Lin, Wu, Chen, Wang, & Chen, 2002; Park et al , 2013; Sarabia Cobo et al , 2015; Schols et al , 2013)</p> <p>37-51% of acute stroke patients have dysphagia (Crary et al., 2013; Gordon, Hower, & Wade, 1987; Mann, Hankey, & Cameron, 2000; Odderson, Keaton, & McKenna, 1995; Smithard, O'Neill, Parks, & Morris, 1996), 50% prevalence in head and neck cancer (Garcia-Peris et al., 2007).</p> |
| 3. | Who usually makes the decision to start someone on fluid thickeners? |

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| | <p>Ideally a SLT, however there are times when other professions make this decision although this is often with limited understanding about the pros and cons of this management strategy. This includes in both inpatient and the community. Occasionally a residential care facility will make a unilateral decision to start someone on thickener however we would strongly argue that the factors that go in to this decision should always be overseen by a Registered SLT.</p> <p>One of the reasons that residential care facilities make these decisions is that in some areas waiting lists for SLT community services can result in thickened fluids being trialled while awaiting an assessment. There is a need to further indicate residential care facilities on the risks of using thickened fluids without a full assessment by a Registered SLT.</p> <p>We strongly recommend that it should be a Registered SLT who makes this recommendation.</p> |
| 3a | How is this decision to start someone, for long term use, on fluid thickeners made? |
| | <p>It's important to note that not all decisions to commence using thickener would be long term decisions. The decision to start thickener would be made on a case by case basis with the patient and their whanau, as well as the medical professional overseeing their care where appropriate. The decision would be considered amongst all management options and with instrumental assessment where appropriate. It is very common for use of thickener to be a short-term, compensatory measure, to support prevention of an aspiration pneumonia, whilst dysphagia rehabilitation can be carried out to facilitate a return to thinner fluids.</p> <p>Where a long term need for thickener is identified, this should always be based on an understanding of the aetiology of dysphagia, and therefore whether it is likely to respond to rehabilitation or spontaneous resolution. There are cases where a dysphagia is progressive and therefore thickener would be a longer term requirement, but again, this decision should always be made under guidance of a speech-language therapist and in conjunction with both the patient and their whanau, as well as the medical professional overseeing their care.</p> |
| 4. | How often is the use of fluid thickeners reviewed? |
| | Case by case basis. This will depend on the individual person, aetiology, and/or progression. There should be clear recommendations around what would prompt a review based on clinical indicators of need. |
| 4a. | How long is someone usually on fluid thickener(s) for? |
| | This varies significantly from a few days to years. It is entirely dependent on aetiology. Some patients post stroke will use these for as little as 24 hours while spontaneous recovery occurs, others will need thickener for longer while rehabilitation occurs. A person with a progressive dysphagia such as that |

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| | associated with Parkinson's Disease, Motor Neuron Disease, Inclusion Body Myositis to name but a few will likely need thickener longer term but even in these cases once they enter a palliative phase or as their dysphagia progresses, thin fluids may once again become the preferred means of meeting hydration requirements |
| 4b | What evidence/guidance/guidelines are used to support long-term use of fluid thickeners? |
| | <p>There is limited research currently found to demonstrate significant consequence or benefit of using thickeners in adults and these studies that have been completed are in limited patient populations which also include populations where the recommendation for thickener has not been made by a SLT as part of a comprehensive swallowing assessment. Therefore this intervention is recommended from clinical work up and assessed patient risk/impact on QOL.</p> <p>Within Paediatrics there are a number of recent articles supporting the use of thickener as an option in the management of dysphagia. Please see bibliography at the end which has been provided by a member of the group.</p> <p>Comparison of the costs of thickener compared to tube feeding which is fully funded needs to be taken in to account As does the cost of thickener compared to hospital readmission where the person is taking risks of aspiration of un-thickened fluids because they are unable to self-fund or access thickener</p> |
| 5 | What are the goals of therapy when using fluid thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life? |
| | <p>Any or all of the above. Dysphagia is always a symptom of disease, rather than a diagnosis. In every case management of dysphagia should be a carefully considered, multi-faceted decision based on pros and cons/risks and benefits of all of the priorities mentioned above.</p> <p>There is an increased risk of dehydration when someone is coughing on thin fluids as they tend to avoid drinking. Thickened fluids is not always the answer but for some patients it makes drinking a much more enjoyable experience and their risk of dehydration is much reduced.</p> <p>In addition funding thickener <i>regardless</i> of location may facilitate earlier discharge from hospital, prevention of readmission and avoidance of tube feeding which improves health outcomes and reduces overall cost to the health system</p> |
| 5a. | How much do fluid thickeners help achieve these goals? |
| | For people in whom use of thickener is indicated, 100% of the time. Thickened fluids, however, are only a part of the clinical management of dysphagia. They are a tool that for some patients are very useful but |

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| | may not be appropriate for others. Thickened fluids are not beneficial in isolation from other factors such as good oral hygiene, careful feeding/assistance for people with dysphagia. |
| 5b | What evidence is available to support this (5a)? |
| | Clinical evidence instrumental assessment, patient report etc |
| 5c | Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia? |
| | <p>Yes, risks include dehydration, constipation and malnourishment, increased risks or reduced effectiveness if the thickened fluids are not prepared correctly, impact on quality life if there is reduced enjoyment with thickened fluids and risk of increased pharyngeal residues. For patients with pharyngeal weakness there may be pharyngeal residues and the risk of pharyngeal residues increases with thickened fluids in many cases. If these residues are aspirated it is more likely to result in pneumonia.</p> <p>For babies and children there is greater potential harm caused by possibly aspirating thickener</p> <p>For these reasons we advocate that thickened fluids should only be prescribed/recommended following a comprehensive assessment of swallowing by a SLT, ideally including objective measures of the benefit or where it has been found to reduce distress from coughing or choking on fluids and positively impacts on quality of life</p> <p>Risks can be further mitigated with education and training on preparing thickened fluids</p> |
| 6. | Are there any people/patient groups where the use of a fluid thickener may prevent the need for a feeding tube? |
| | Yes |
| 6a | If so, which people/patient groups? |
| | Each person is evaluated on a case by case basis and it is not directly related to aetiology All patients that are evaluated at a high risk of developing an aspiration pneumonia, the use of thickener is inline with their goals and they are medically appropriate |

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| 6b | For how long would the use of fluid thickeners delay the need for a feeding tube? |
| | This is difficult to define as every person is different. For some people it could prevent the need for a feeding tube entirely. |
| 7. | How is someone's quality of life improved by a fluid thickener? |
| | <p>It is difficult to comment on someone else's quality of life. There have been many cases where individuals have reported that being able to use thickener for fluids allowed them to enjoy a cup of tea/coffee again, and even on a few occasions a beer/whisky - which made a huge difference to their quality of life.</p> <p>If aspiration is causing discomfort/embarrassment i.e. coughing often or repetitive acute illness such as pneumonia and thickened fluids prevents this happening then sometimes the change of the fluid consistency is out-weighed by the overall improvement they have in their lives.</p> |
| 7a. | How is any improvement in quality of life demonstrated or measured? |
| | Patient and/or carer reporting as well as desire to continue with that same management plan on review. |
| 7b. | What evidence is available to support this? |
| | Unsure if there are specific scientific papers to support this and patient/carers self reporting is the only method in use able to collect this information. As SLTs we always have strong ongoing relationships with patients when we make these changes and they will often report how much better they feel to have thickened fluids as an option now. |
| 8 | Are there any other available products (funded or unfunded) that achieve the same goals as fluid thickeners aim to achieve? |
| | Pre-thickened fluids are available, though variably tolerated, significantly more expensive and also unfunded. A benefit of a thickener is a person can thicken their own preferred beverage to the prescribed thickness, thus supporting the goals of both improved quality of life and hydration/nutrition. |

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| | Water only guideline is an option for many patients instead of using thickener and one that is now used routinely as part of a suite of options offered to patients to meet both safety and quality of life goals, however this guideline is not ideal for patients with severe cognitive impairment, or where they have difficulty completing or poor oral cares or where there is very high risk of pneumonia or the patient's overall health/ co-morbidities put them at greater risk of infection. |
| 9. | We are aware of a range of different types of fluid thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals? |
| | <p>The ones that work well – yes they all achieve the goal of preventing/reducing aspiration risk. However, other goals such as independent preparation of fluids, maintaining hydration orally and consistency of preparation may be impacted by the ease of use, palatability and stability of different types of thickeners. Thickening powders are more complicated to use, clump, are not stable (thicken over time) and are less hygienic compared to liquid thickeners. Gum based and starch based thickening powders also differ in their attributes. Starch based thickeners are difficult to use in bottle feeding with babies due to instability of the products. Natural thickeners are not standardised to specific consistencies and may result in inconsistency in preparation and potential risk to the patient.</p> <p>In our experience and following repeated trials at some DHBs liquid thickeners are by far the most well tolerated (and therefore adhered to) and easiest to use</p> |
| 9a | Are there different benefits associated with different types of fluid thickeners? |
| | <p>The adult and paediatric populations are significantly different in terms of what thickener is safe. In the paediatric population there are limited brands that have been approved as safe to use with babies.</p> <p>For adults, in general the liquid thickeners are most cost-effective, easiest to use, least prone to incorrect dosing and because of all of these things, most likely to result in a higher rate of compliance and therefore admission avoidance, lower rate of aspiration, higher quality of life, and higher adherence to nutrition and hydration goals</p> <p>In certain circumstances there has been the rare use of thickener in the absence of dysphagia for the treatment of reflux in the paediatric population.</p> |
| 10. | Any other comments |
| | There are significant financial barriers to purchasing and using thickeners for some people. This may lead to people not using thickeners resulting in detrimental health outcomes, e.g. potential admissions to |

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| | <p>hospital and increased costs to the health system should the person become reliant on tube feeding as an alternative.</p> <p>Māori and Pasifika people are disproportionately affected by chronic conditions, respiratory conditions and stroke where dysphagia is likely to be a presenting feature. Enabling improved access to thickeners recommended by SLTs would help to improve equity for these populations.</p> <p>It needs to be highlighted that equitable access to thickener, or the ability of a patient to afford/access thickener, may adversely impact our clinical decision making. For example, if a patient expresses concern that they are unable to afford thickener we will always try to pursue alternative options (e.g. water only with acceptance of increased risk of aspiration and potential for admission to hospital) but this might be in contradiction to the results of our clinical assessment.</p> <p>Recommending risk feeding as a result of financial limitations is a common challenge for SLTs, across DHBs and populations, and one of the most worrying aspects of our ability to manage patients with dysphagia. If thickener was funded this would increase equitable access and mean our most vulnerable patients are not at relatively higher risk.</p> |
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1. In what clinical situation would a person be started on a food thickener?
 - a. Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

Paediatric clients:

The most likely clinical situation for starting a food thickener would be a child with recurrent respiratory illnesses who demonstrated aspiration or penetration during Videofluoroscopic Study of Swallowing (VFSS) and who demonstrates reduction in these markers with trial of thickened liquids during the study.

"A well-executed videofluoroscopy study not only provides evidence for aspiration but will also explore relative risks for different consistencies of feed and optimal posture during feeding. Advice regarding volumes, cups, spoons, bottles and teats, posture, thickeners, and consistency can significantly improve the aspiration risk and consequent lung health." (Wallis C, 2012)

As regards severity "Although aspiration is considered more pathologic than penetration, penetration is also associated with risk for pneumonia" (Gurberg J, 2015)

The emerging evidence suggests that: "Thickening or other feeding intervention should be considered for all symptomatic children with laryngeal penetration on VFSS." (Duncan D R, 2019)

Another clinical situation that may present would be where a child is not able to manage thin liquid orally due to inco-ordination often in the presence of neuromotor impairment e.g. cerebral palsy. Thin liquid may spill out of the mouth due to lack of oral control. Thickening may enable the child to maintain oral intake as the slower flow of the liquid may support better oral control and safe swallowing

- 2 How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)?
 - a How many people might have dysphagia and benefit from the use of food thickeners?

In our small-medium DHB we have completed 17 VFSS in 2020 and thickener was recommended for 8 of these patients, approximately 50%. No thickener for paediatric patients is currently funded through Pharmaceutical Schedule. These patients may be eligible for a disability allowance to fund expenses like thickener.

- b. How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners?

Not applicable for paediatric patients.

3. Who usually makes the decision to start someone on food thickeners?
 - a. How is this decision to start someone, for long-term use, on food thickeners made?

Paediatric Speech Language Therapists will recommend thickening based on the outcome of the Videofluoroscopic Study of Swallowing in liaison with the MDT and with consideration of the full clinical presentation.

4. How often is the use of food thickeners reviewed?
 - a. How long is someone usually on food thickener(s) for?

This is highly variable from a few months to several years.

“Oropharyngeal dysphagia can also occur in infants without any detectable risk factors who present with unexplained respiratory problems. This may represent some form of delay in the maturity of their swallowing integrity. The prognosis for resolution in these children is good, although it can take years. (Wallis C, 2012)

“Laryngeal penetration is not transient in children under 2 years of age and may be indicative of aspiration risk.” (Duncan D R, 2019)

In children with neuromotor impairment there is frequently not resolution, but feeding therapy, including the use of thickener, may optimise oral intake with reduced mortality and morbidity. In these patients thickening may be needed throughout their lifetime at significant personal cost.

- b. What evidence/guidance/guidelines are used to support long term use of food thickeners?

We are consistently being led by emerging evidence from the literature, by clinical experience and by patient experience.

- c.

Thickening is consistently reviewed for tolerance and the impact on intake, gastro intestinal effects, allergic responses and symptom reduction. This is done in liaison with Dietitians and the wider MDT team. Once it has been established that thickening is well tolerated and achieves the therapeutic goals there will usually be at least annual review.

5. What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?
 - a. How much do food thickeners help achieve these goals?

“The goals of feeding therapy are to provide nutrition safely and efficiently, prevent lung injury, preserve respiratory function, and permit appropriate growth.” (Das S, 2020)

“The lung is the primary end organ of damage secondary to aspiration. The injury may occur anywhere along the respiratory tract but most consistently results in chronic bronchiolar inflammation and injury, in a dependent distribution. Bronchiectasis is a common result and may develop even in infants.” (Piccione J C, 2012)

- i. What evidence is available to support this?

In their May 2019 “Clinical Aspects of Thickeners for Paediatric Gastroesophageal Reflux and Oropharyngeal Dysphagia” Duncan R et al provides a summary of reported effect of thickening feeds in studies completed between 2001 and 2018. (Please see article: Table 1) (Duncan D R, 2019)

A study by the same authors “Feeding interventions are associated with improved outcomes in children with laryngeal penetration” adds to this in that their subjects had “decreased total and pulmonary hospitalizations with feeding intervention and decreased pulmonary nights with thickening. (Duncan D R, 2019)

- b. Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

For a recent summary of risk factors see discussion on risk in abovementioned article. (Duncan D R, 2019)

In their risk:benefit analysis the authors conclude that: “ From an oropharyngeal dysphagia perspective, the alternative to thickening would involve continued aspiration with increased pulmonary morbidity, hospitalizations, and ER visits in addition to increased placement of enteral tubes; again the thickening safety profile relative to the alternatives is favorable.”

Risks are also discussed in the 2020 literature review-UpToDate- (Das S, 2020) and the author concludes that “Use of thickeners is generally low risk, but a few safety considerations have been raised:”

6. Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube?
 - a. If so, which people/patient groups?

Paediatric patients with recurrent respiratory illnesses and hospitalisation who may not be able to manage oral thin liquids but who may be able to manage thickened liquids safely.

Paediatric patients who may not be able to manage the full volume of liquids required as thin fluids but who may be able to increase their intake with thickened liquids e.g. patients with cerebral palsy.

It also needs to be considered that “Use of thickeners for oral feeding has been shown to reduce respiratory symptoms and hospitalizations compared with unmodified feeds and even compared with infants being fed via gastrostomy.” (Das S, 2020)

b. For how long would the use of food thickeners delay the need for a feeding tube?

If therapeutic goals are met by thickening for children with respiratory symptoms feeding tubes can be avoided completely.

“Thickening of feeds can even reduce the need for gastrostomy tube placement in children with aspiration” (Duncan D R, 2019)

In some children with neuromotor impairment there may be need for tube feeding if their growth needs outweigh their ability to take in sufficient nutrition.

7 How is someone’s quality of life improved by a food thickener?

Recurrent respiratory illnesses and hospitalisation in a baby or child not only affects the quality of life of the child, but that of the whole family. Recurrent illness and hospitalisation impacts on the physical wellbeing of the child and in young babies and children on their development. Young children may miss out on educational opportunities.

There is an emotional impact on the parents and extended family in terms of dealing with recurrent illness in their child; there is significant financial impact on the family. Many of our families need to travel up to 2 hours to their regional hospital and transfer to the base hospital will incur further traveling expenses. There is the social burden of care for other children when the parents need to spend time in hospital with an unwell child and not being able to maintain their work/business life. Chronic illness can impact on the mental health of parents and caregivers.

Prevention of tube dependency can also enhance quality of life in that there is reduced need for medical interventions e.g. frequent home/hospital visits to replace and/or manage tubes; normalisation of home and social life.

Maintenance of eating and drinking in the child with neuromotor impairment (disability) will enhance their quality of life through reduced medicalisation and enhanced ability to participate in home, community and educational activities.

a. How is any improvement in quality of life demonstrated or measured?

Improvement is primarily measured in terms of reduced respiratory symptoms and reduced hospital admission which will impact on all aspects of quality of life.

b. What evidence is available to support this?

The emerging evidence suggests that: “Thickening of liquids and, to a lesser extent, reduction in flow rate reduce symptoms and respiratory hospitalizations. This has been demonstrated both in infants and young children who have aspiration on videofluoroscopic swallow study(VFSS) and those with penetration alone” (Duncan D R, 2019)

- 8 Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve? No
- 9 We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?
Yes some thickeners are not recommended for babies and children.
 - a. Are there different benefits associated with different types of food thickeners?
No
- 10 Any other comments?

Babies/children of Maori and Pacific Island descent are disproportionately affected by respiratory illnesses and the progression of illness to chronic disease in New Zealand.

Uninterrupted maintenance of thickening of feeds, where it is indicated, is essential to ensure that babies/children benefit from the intervention.

The cost of thickeners impacts on the ability of low income families to maintain uninterrupted maintenance of thickening for their babies/children and can therefore directly impact on their health.

Thickeners are not readily available for purchase in many communities, especially smaller towns and rural areas in New Zealand and online purchases are frequently not an option for families with low resources as regards finances, internet access etc. Families with limited resources are therefore left at a disadvantage having to negotiate with local pharmacies to secure a continuous supply of thickener

Easier access to thickener will also support the MOH initiative to reduce Ambulatory sensitive hospitalisations (ASH) i.e. admissions that are reducible through prophylactic or therapeutic interventions

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From: Anna Ranta <[redacted]>

Sent: Friday, 12 March 2021 3:02 pm

To: Consult <Consult@Pharmac.govt.nz>

Subject: Food Thickeners

Kia ora

My name is Prof Anna Ranta and I am a stroke neurologist and current president of the Neurological Association of New Zealand. While the views below are my own and I have not had an opportunity to circulate the below to our membership, I have actively sought input from other neurologists in NZ on this topic reporting my strong support for making these thickeners available to patients who need them (based on SLT assessment) and I have had no dissenting views expressed after my request for feedback

I am not an expert in swallowing assessment, but I am an expert in stroke management and have previously run motor neuron disease multidisciplinary meetings. Many of my patients benefit from food thickeners, primarily in the short term. Most patients either fully recover or require long-term tube feeding. But some people hover in between and sometimes for many years. These people, in my opinion, are greatly aided by access to food thickeners. I provide more detail below also aiming to answer your specific questions

From our own clinical and research experience we know that stroke patients who undergo a formal swallowing assessment within 6 and 24 hours of admission have better long-term outcomes. The nursing team completes an initial screen within 6 hours and if the patient fails the SLT will perform a more formal test within 24 hours whenever possible. When swallow screen is failed it is routine to add thickeners to liquids because thick liquids are particularly difficult to manage for stroke patients and have a higher risk of aspiration and subsequent pneumonia – one of the most common complications and causes of death following stroke. Generally a fairly standard protocol is used initially, but if problems persist SLTs will employ videofluoroscopy where patients are given different types of food consistencies to determine what is and what is not tolerated by an individual patient. This then guides longer term therapy and can be reviewed intermittently. Most patients regain the ability to swallow normal foods eventually but a few do not. For stroke we have about 8000 in NZ each year of which about 50% achieve independence and 36% die by 12 months leaving 14% with some disability. Of these probably only about 5% require long term food thickeners as most will either be able to tolerate a normal diet or be fed via a PEG tube (very low%). This would mean perhaps 56 new patients per year on thickeners from stroke. With this support we can achieve the best long term outcome for patients. We recently uncovered that care in provincial hospital often lack specialist SLT and other care as well as care in an acute stroke unit and that this is associated with a significantly poorer chance of survival in the long run. It is pretty clear that SLT support, swallow assessments, and appropriate food consistency play a role in this and is thus important for these patients

Motor neuron disease is the main other adult condition that requires food thickeners from time to time. In NZ about 150 people are diagnosed each year with MND and the median life expectancy is 29-48 months from diagnosis. Most people probably only need food thickeners during the last 3-6 months and probably only about 50% ever require these as many rapidly shift to PEG tubes or palliative care. So I would expect only about 50 patients (if that) on thickeners at any given time. These are very much back of the envelope calculations, but based on my estimate I'd think perhaps 200 people in NZ require these per year. Stroke patients live longer on average than MND patients but life expectancy is generally short after a significant stroke and even if on average those who have not died by 12 months live another two years or require dysphagia support for another two years the

annual number of patients who require this support would likely be on the order of 350 adults across new Zealand. I cannot comment on children.

I would estimate that about half of the people requiring food thickeners live in care facilities

It is usually a qualified speech and language therapist that makes the decision to start food thickeners. Decisions are made on their assessment including videofluoroscopy as per process outlined above. Same applies to MND.

I don't think that there is a standard review period, but it would seem reasonable to me that post discharge the need should be reviewed initially 3 monthly, then six monthly and if someone has needed them for more than two years probably yearly.

Goals of therapy are primarily to achieve someone's nutritional/hydration needs without increasing the risk of aspiration and avoiding tube feeding. Sometimes patients get tube feeding and the thickeners are used to provide supplemental oral input for quality of life reasons, but that is not the usual primary goal. However, food thickeners may have the added benefit of reducing patient anxiety about aspiration. Again this is not the primary goal in most cases though. Food thickeners often make the difference between requiring a feeding tube or not. Without them those people who need them generally will eventually aspirate and get a pneumonia which can cause not only hospitalisation but also death. I am not aware of any risks associated with food thickeners.

See comments above – yes there are both stroke and MND patients (as well as a few other rarer neurological conditions) where food thickeners can prevent tube feeding.

I am not aware of any alternatives to food thickeners and there are no medical treatments to improve swallowing function

I am sorry I do not know which thickeners are the best. Specialist speech and language therapists would be best placed to comment on this and may have additional evidence they could provide.

I acknowledge that my understanding of the detailed literature on this topic is limited beyond the benefit of SLT assessments in acute stroke patients and probably the most expert opinions will come from SLTs on this topic. However, I thought it might be helpful to you to hear my opinion and experience and if you felt that further conversation with me would be helpful I do not mind to be contacted via email.

Ngā mihi nui.

Anna

Professor Anna Ranta, MD, PhD, FRACP, FAHA, FWSO | Head of Department - Department of Medicine - University of Otago, Wellington | CCDHB and Central Region Stroke Lead & Consultant Neurologist - Department of Neurology Capital & Coast DHB | Address: Department of Medicine, University of Otago, Wellington, 23a Mein St, Newtown, PO Box 7343, Wellington 6021 | Mobile: Withheld under section 9(2) | Email: Withheld under section 9(2) | Zoom: Withheld under section 9(2)(a)

From: Donnelly, Sarah, MULGRAVE, Sales <[REDACTED]>
Sent: Friday, 12 March 2021 4:46 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: PHARMAC: Funding of food thickeners – seeking information
Importance: High

To whom it may concern,

Please find attached the feedback from Nestle Health Science on the funding of food thickeners as requested by PHARMAC.

Should you have any further questions, please do not hesitate to contact me.

Kind Regards
Sarah



Sarah Donnelly | Medical Nutrition Category & Channel Sales Development Manager
| Nestle Australia Ltd, Suite 2 / Level 1, 8 Nexus Court, Mulgrave, VIC 3170
| M [REDACTED]
| E [REDACTED]

NEW

RESOURCE® ULTRA
A new addition to the clear, fruit flavoured beverage range

- 100% whey protein
14g per serve (highest in its category)*
- 300 kcal of energy per serve
- Apple and Orange fruit flavours

*RESOURCE® ULTRA contains the highest amount of protein per serve, compared to other clear fluid oral nutritional supplements available in Australia, April 2020, based on label nutrition information.

RESOURCE® ULTRA is a food for special medical purposes specifically formulated for medical conditions where nutritional needs cannot be met through diet modification alone. Must be used under medical supervision.

Dysphagia is the medical term for difficulty swallowing. It can lead to malnutrition, dehydration, reduced quality of life and choking. It is a distressing condition for patients as eating and drinking is an essential everyday activity, which is fundamental for survival, and generally enjoyable. However, for people who develop dysphagia it can make mealtimes a challenge rather than a pleasure. Dysphagia occurs in all age groups, but its prevalence increases with age. Dysphagia is usually caused by another health condition for example stroke, head injury, ageing or a progressive condition, e.g. Parkinson's Disease, Multiple Sclerosis, Motor Neuron Disease, Alzheimer's, Muscular Dystrophy, Cerebral Palsy, Huntington's Disease or head and neck cancers. Symptoms include:

- The inability to recognise food
- Difficulty placing food in the mouth
- Inability to control food or saliva in the mouth
- Difficulty in initiating a swallow
- Food sticking in the throat or chest
- Discomfort or severe pain
- Frequent chest infections
- Unexplained weight loss
- Regurgitation, vomiting, coughing and choking.

Prevalence of dysphagia

The prevalence of dysphagia and its complications are more common than one may realise, and it affects over 590 million people worldwide (8% of the population)¹. Looking at different settings, dysphagia is present in:

- Approximately 13% of people in the community²
- Approximately 25% of patients in hospitals²
- At least 60% of elderly residents living in long-term care facilities²

A New Zealand study by Wham et al, looking at malnutrition risk across different settings, found that 32.1% of the aged care residents in the study were at risk of dysphagia, and 3.5% in the community³

Although dysphagia may be prevalent in the ageing population due to deterioration of muscle and mechanical issues, it also affects:

- 50% of head and neck cancer patients⁴
- 25–81% of stroke patients⁵
- 15–87% of Parkinson's disease patients⁶
- 32–93% of Alzheimer's disease patients⁵

It is recognised by the European Union of Geriatric Medicine Society (EUGMS) in a white paper that dysphagia is often underdiagnosed and untreated⁵.

International standards for thickened fluids and modified texture diets

The importance of thickened fluids for managing individuals with dysphagia is well recognised and been used for 19 years². As people with dysphagia have difficulty controlling the fast flow of thin liquids as it passes through the pharynx, providing thickened fluids aims to slow the flow of the liquid, allowing the individual time to coordinate a safe swallow. In order to thicken a fluid to a suitable viscosity, a safe and palatable food thickener is required. As previously mentioned, the prevalence of dysphagia is significant in the community as well as in institutional settings such as hospital and aged care facilities, therefore the availability of appropriate food thickeners is essential in the management of dysphagia.

Various standards and naming conventions have been used around the world for prescribing appropriate thickened fluids for dysphagia. Due to the discrepancy internationally, in 2013, the International Dysphagia Diet Standardisation Initiative (IDDSI) committee was formed. Their goal was to develop international standardised terminology and descriptors for dysphagia diets that would meet the needs of individuals with dysphagia across the age span, across all care settings and across all cultures (Figure 1: The IDDSI Framework). The two primary reasons for pursuing international standardised terminology were to improve patient safety, and for evolution of the field of dysphagia to deliver better treatment outcomes¹.



Figure 1: The IDDSI Framework¹⁶

The IDDSI board consists of experts and key opinion leaders in the area of dysphagia, all whom recognise the need for thickened liquids and modified texture foods for people with dysphagia. The board includes speech pathologists, dietitians, an occupational therapist, ENT, physician, engineer and food scientist from around the world.

The IDDSI Framework has been developed and is being implemented in over 30 countries, with strong support from speech and language therapy associations.

In 2015, a systematic literature review was published on the influence of food texture and liquid consistency modification on swallowing physiology and function⁷. The authors concluded that evidence shows a benefit associated with thickening liquids in terms of reducing penetration and aspiration, however it also brings with it a risk of post-swallow residue in the pharynx with thicker consistencies. The literature strongly suggests that there are several relevant

properties of food texture for swallowing, including cohesiveness, hardness, and slipperiness. This review has helped to form the IDDSI standards to ensure safety for people with dysphagia across the globe.

Important role of food thickeners for people with dysphagia

As mentioned earlier, not only can dysphagia cause dehydration and malnutrition, but it can also result in aspiration pneumonia, which can in turn cause increased morbidity and mortality. At the extreme end of the spectrum, dysphagia can also result in choking, airway obstruction and death. Furthermore, dysphagia can lead to depression and deterioration in the quality of life for the individual.

Thickeners are recommended and prescribed for the treatment of dysphagia; they are used to thicken both liquids and foods to various consistencies. The passage of liquids and foods consumed tends to be fast and turbulent; the food thickener helps to slow down transit to allow the patient more time to coordinate the swallowing process safely. This helps to prevent the liquid or food from entering the lungs, which can cause serious complications such as chest infections and death due to choking or aspiration pneumonia, and therefore reduces hospital admissions, length of hospital stays or risk of death. There are many different brands of food thickeners available on the market; some contain starch whilst others contain gums. The recommendation to prescribe a food thickener should come from a speech pathologist and should be based on the patient's degree of dysphagia, the food and fluid modification required, palatability and cost-effectiveness amongst other considerations.

Thickened foods and fluids make swallowing easier and safer for patients with dysphagia. Starch-based products thicken foods and liquids by swelling up, whilst gum based thickeners form a mesh in which water molecules become entangled. Starch-based thickeners were common and previously prescribed as they have been available longer and are cheaper, however studies have demonstrated that they tend to have an undesirable "starchy" flavour, a grainy texture and can form lumps when mixed with fluids. This makes them less likely to be tolerated and reduces compliance. Fluids thickened with a starch-based thickener tend to be unstable and continue to thicken over time. Alternatively, if they are mixed with saliva, they can become thinner as they are broken down by the enzyme amylase found in saliva, which reduces the effectiveness of the thickened food or fluid and poses a safety risk to the patient. Gum thickeners maintain their thickness as they are resistant to amylase which makes them safer for patient use. Gum thickeners have a smoother texture; they are less grainy and tend to be preferred by patients as they are more palatable which improves adherence and hydration. Food thickeners are an effective way to help people with dysphagia swallow fluids and eat foods safely.

There are several commercially available food thickeners on the market across Australia and New Zealand. Some are starch based, and some are gum based, some are used to thicken food only and others are indicated to thicken both foods and fluids. When thickening foods and fluids it is important that only the scoop provided with the food thickener is used as these can vary between different products. Using the correct scoop will enable the correct amount of food thickener to be mixed with the correct amount of food and fluids. Always follow the manufacturer's instructions to enable the correct consistency to be achieved to the prescription. This will help patients and carers at home mix the food thickener correctly and ensure the instructions are added to the clinical records for residents in care homes.

Clinical evidence for the use of RESOURCE THICKENUP Clear

RESOURCE THICKENUP Clear is an exclusive xanthan gum based powdered food thickener available from Nestlé Health Science, used in the management of dysphagia. The benefits of RESOURCE THICKENUP Clear as compared to a starch based thickener include preserving the natural appearance of the food and fluid being thickened, ease of preparation and efficacy reported in several published studies

Improvement in swallowing safety with RESOURCE THICKENUP Clear

Numerous studies have shown that using RESOURCE THICKENUP Clear to thicken fluids for people with dysphagia can help to improve the safety of swallow.

As compared to thin liquids, Rofes et al⁸ demonstrated that RESOURCE THICKENUP Clear effectively:

- Improves swallowing efficacy, oral control and the ability to form a bolus;
- Improves swallowing safety: reduces aspiration and penetration without increasing oropharyngeal residue.

Vilardell et al⁹ compared both a starch-based thickener with RESOURCE THICKENUP Clear in stroke patients with dysphagia. While both thickeners improved the safety of swallow, RESOURCE THICKENUP Clear did not increase the prevalence of oral and pharyngeal residue, better avoiding the risk of aspiration after the swallow.

Leonard et al¹⁰ compared a thin liquid barium contrast fluid with the same fluid thickened with a starch based thickener and RESOURCE THICKENUP Clear and found that RESOURCE THICKENUP Clear significantly reduced the risk of aspirations and therefore improved swallowing safety in patients with dysphagia.

Accurate assessment with RESOURCE THICKENUP Clear

RESOURCE THICKENUP Clear may also be used as a food thickener in the assessment of dysphagia. Studies by Popa Nita et al¹¹ and Rofes et al¹² demonstrate that RESOURCE THICKENUP Clear can be used to thicken common videofluoroscopic contrast agents to aid in the accurate assessment of dysphagia.

Compliance and tolerance with RESOURCE THICKENUP Clear

A real-world study was completed in 2011 to assess the acceptance and tolerance of the use of RESOURCE THICKENUP Clear as a part of everyday dysphagia management in an aged care facility¹³. A high degree of satisfaction was observed with RESOURCE THICKENUP Clear on the basis of its sensory characteristics, good compliance, excellent gastrointestinal tolerance and wide versatility in use with different drinks at different temperatures.

QUESTIONS FROM PHARMAC

In what clinical situation would a person be started on a food thickener?

As dysphagia can be present itself after a medical incident, or with ageing, it is common for individuals to require a food thickener to aid in the management of dysphagia in the hospital setting, long term care setting, and also at home in the community.

Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

For those with dysphagia, eating and drinking safely is problematic. The fast flow of liquid is difficult to control as they pass through the pharynx, resulting in impaired airway protection. One of the methods of managing this challenge is to thicken liquids so they flow more slowly, allowing time to coordinate a safe swallow². Thickened liquids are not a diet of choice, but one of safety, and have been used therapeutically to manage dysphagia for about 19 years².

Upon assessment with a speech pathologist, a suitable modification to the diet will be made to liquids, foods or both. Many people with dysphagia will benefit from a food thickener to thicken liquids, however the speech pathologist will determine the level of thickness required, based on the severity and type of dysphagia.

Dysphagia symptoms can be identified with the EAT-10¹⁴ swallowing screening tool, and clinical signs and care needs can be evaluated by performing a bedside Volume Viscosity Swallow Test (V VST).¹² A videofluoroscopy may also be performed to diagnose dysphagia

How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)?

The amount of food thickener required by each patient per month will vary, and so will the cost, depending on the quantity of fluid they consume, and the consistency required.

Food thickeners should be prescribed by the tin as this is the most cost-effective option rather than sachets or pre-thickened drinks. In addition to cost, the choice of food thickener should be based on the individual patient preference regarding flavours and textures, the food and fluids should look appetising and taste palatable to encourage compliance and avoid dehydration. Gum based clear thickeners tend to be preferred by patients as they are more palatable, stable and safe. This improves compliance and therefore reduces both waste and costs. If residents in care homes have clearly documented details of the consistency required in their clinical record or management plan, consider if bulk prescribing would be appropriate to avoid waste and reduce costs.

How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners?

Over 35,000 people live in residential aged care facilities (RACFs) in New Zealand¹⁵. A study by Miles et al in 2020 showed that approximately one third of these residents are on texture modified diets. Although all these residents may not have dysphagia, this indicates that there may be approximately 10,000 residents who are on texture-modified foods and/or thickened fluids. These residents would benefit from having appropriate food thickeners available to help thicken foods and fluids to allow a safe swallow.

Who usually makes the decision to start someone on food thickeners?

When an individual is displaying symptoms of dysphagia, that person will be assessed by a Speech Pathologist. The Speech Pathologist will then determine the requirement for a food thickener to be used to thicken fluids, as well as the level of thickened fluids they require. This will be based on the IDDSI standards¹⁶, as mentioned previously.

How is this decision to start someone, for long-term use, on food thickeners made?

After assessment, the Speech Pathologist will prescribe a suitable modified texture diet, based on the IDDSI standards¹⁶. If they determine that liquids need to be thickened, then an appropriate food thickener will be required.

How long is someone usually on food thickener(s) for?

It may be short-term while they are recovering from an incident or surgery, or it may be lifelong if their dysphagia is irreversible or their clinical condition is progressive such as Parkinson's Disease, Multiple Sclerosis, Motor Neuron Disease and Muscular Dystrophy.

What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?

The consequences of dysphagia are numerous and can be severe. They include malnutrition, aspiration, dehydration, pneumonia, and death. The use of food thickeners to thicken fluids as well as help with texture-modification of foods can help to decrease the risk of such consequences by improving the safety of the swallow.

Dysphagia can:

- Increase the risk of malnutrition, with approximately 50% of older patients being malnourished or at risk. Those with pneumonia are at even greater risk¹⁷.
 - When malnutrition and dysphagia are combined, the risk of death in older adults is increased⁴.
- Increase the risk of pneumonia by 3 times in stroke patients, which increases to 11 times if the patient presents aspirations⁸.
 - Aspiration pneumonia is associated with a 3-fold increased risk of death compared with stroke patients without pneumonia⁸.

Dehydration is a common concern for people with dysphagia. Dehydration increases the chances of falls, the risk of renal failure, constipation, urinary tract infections, impaired mental status, respiratory infection, poor muscle strength and ulcers associated with being bed bound². Research shows that the addition of gum and starch-based thickeners do not affect the bioavailability of water, demonstrating that water is absorbed from thickened fluids and can aid in the hydration of people with dysphagia.²

How is someone's quality of life improved by a food thickener?

The use of a food thickener in liquids for someone with dysphagia can help to improve their quality of life by reducing the incidence of coughing, choking, spluttering, and pain. This in turn improves the enjoyment of beverages, an important part of socialisation as well as fundamental to survival.

Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve?

We are not aware of any other products that achieve the same goals as food thickeners. It is very important to ensure that the provision of food thickeners to thicken fluids for dysphagia are safe as well as effective. Although many foods can be used to thicken beverages, the beverage must not be overthickened as this can be dangerous for the patient. A thickener which reaches the desired consistency and does not thicken over time is the most appropriate. As well as safety, the beverage needs to maintain its taste and visual appeal, otherwise the patient will not consume it, resulting in dehydration.

Where possible residents in care homes should use the same brand of food thickener to prevent confusion and limit the potential for preparation error amongst care staff

We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?

Many foods can be used to thicken liquids; however, it is essential that the thickener used is proven to be safe as well as effective. A food thickener not only needs to reach a desired consistency to improve the safety of the swallow for someone with dysphagia, but also needs to remain at the desired consistency over time. A liquid that is too thick can be as dangerous as a liquid that is too thin¹⁸. As well as safety, the thickened liquid should retain as many sensory characteristics of the unthickened fluid as possible, to ensure that the individual is able to tolerate and enjoy the liquid. Palatability will improve consumption and therefore assist with hydration and nutrition. Therefore, it is important to use food thickeners that have been specifically evaluated for the use in patients with dysphagia, that have usage instructions that are aligned with IDDSI standards.

Gum based thickeners are recommended over starch based thickeners, as they are more stable (do not thicken over time) and palatable, improving the likelihood of a safe consumption.

Are there different benefits associated with different types of food thickeners?

There are currently two broad types of thickening agents that have been studied, which are both powdered:

- Starch-based thickening agents: added to an aqueous solution, the starch granules capture water inside a polymer structure, increasing in size and establishing physical chemical interactions with the components of the structure to raise viscosity. The final viscosity depends on the time that passes after preparation and the temperature of the mixture.
- Thickening agents based on xanthan gum: added to an aqueous solution, the soluble fibre dissolves and hydrates very rapidly, producing high viscous mixtures in low concentrations. Uniform, highly stable solutions result under different temperature and pH conditions.

Although both powdered thickeners achieve the same goal of improving the safety of swallow, xanthan gum thickeners have been shown to be superior. Beneficial features include preserving the natural appearance of the food and drink being thickened, ease of preparation and efficacy reported in several published studies^{8,9,10,11,12,13}.

Summary

Food thickeners are indicated for the treatment of dysphagia and act by slowing down the transit of food and fluids to allow the patient more time to coordinate the swallowing process safely. This helps to prevent the liquid or food from entering the lungs which can lead to serious complications such as chest infections and death due to choking or aspiration pneumonia. The recommendation to prescribe a food thickener should come from an appropriately trained healthcare professional, such as a speech pathologist.

The choice of food thickener should be based on the patient's degree of dysphagia, desired consistency required, the texture required, palatability and cost-effectiveness amongst other considerations. Gum based thickeners such as RESOURCE THICKENUP Clear is a preferred choice as it is palatable and safe. The most cost-effective food thickeners are available in cans rather than sachets or pre thickened drinks and can be used to thicken a variety of foods and fluids for social enjoyment.

Food thickeners should be prescribed in appropriate quantities to avoid over-ordering, leading to stockpiling and waste or under-ordering, which may put patients at risk, cause care homes to order mid cycle, and borrow from other residents. Bulk prescribing of food thickeners could be considered for care homes if residents have clearly documented details of the consistency required in their clinical record or management plan to avoid waste and reduce costs. A resident's record or management plan should be reviewed to ensure it clearly documents the texture modified foods and fluids that the resident can manage, as well as the duration of treatment, as dysphagia can be a temporary or permanent condition.

Supporting Resource Attached

- Nestle Nutrition Institute. How and why thickened liquids improve swallowing safety and efficiency. Clinical Nutrition Highlights 2021; Vol 1; Issue 1.

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CLINICAL NUTRITION HIGHLIGHTS

Science supporting better nutrition

2021. Volume 1, Issue 1

**How and why
thickened liquids
improve swallowing
safety and swallowing
efficiency**



CLINICAL NUTRITION HIGHLIGHTS

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2021. Volume 1, Issue 1



How and why thickened liquids improve swallowing safety and swallowing efficiency

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0. Abbreviations & Glossary

Abbreviations

| | |
|-----------------------|--|
| Aliquot | A portion of a larger whole sample |
| cP | Centipoise |
| CAD | Canadian Dollar |
| CI | Confidence interval |
| CSE | Clinical swallowing evaluation |
| EDS | Eating drinking or swallowing |
| Efficacy | Ability to produce the intended result of the intervention |
| Swallowing Efficiency | Swallowing action resulting in complete clearance of the bolus from the oral cavity or pharynx. An efficient swallowing mechanism does not leave residue |
| ENT | Ear nose and throat |
| ESPEN | European Society for Clinical Nutrition and Metabolism |
| FAO | Food and Agriculture Organization of the United Nations |
| FEES | Fiberoptic endoscopic evaluation of swallowing |
| FSMP | Food for Special Medical Purposes |
| ID | Intellectual disability |
| i.v. | Intravenous |
| LOS | Length of stay |
| mPa.s | Milli-pascal-seconds |
| ms | Millisecond |
| MBSS | Modified barium swallow study |
| MJ | Mega Joule |
| Newtonian Fluids | Fluids where the force required to make the fluid flow is proportional to the resulting amount of flow |
| NICE | National Institute for Health and Care Excellence |
| NMES | Neuromuscular electrical stimulation |
| OD | Oropharyngeal dysphagia |
| ONS | Oral nutritional supplement |
| PAS | Penetration-Aspiration Scale |
| PEG | Percutaneous endoscopic gastrostomy |
| RDI | Reference dietary intakes |
| Residue | Liquid or solid that remains in the mouth or throat after the swallow |
| Rheology | The study of the deformation and flow of matter |
| Swallowing safety | Risk for material entering the airway or the entrance to the airway, measured on the PAS |

| | |
|-------|--------------------------------------|
| SLP | Speech and language pathologist |
| SLT | Speech and language therapy |
| TMF | Texture-modified food |
| UES | Upper oesophageal sphincter |
| UL | Upper Intake Level |
| US | United States of America |
| USD | US Dollar |
| VFS | Videofluoroscopy |
| VFSS | Videofluoroscopic swallowing studies |
| V-VST | Volume-viscosity swallow test |
| WGO | World Gastroenterology Organization |

Glossary

| | |
|-------------|--|
| Bolus | A discrete rounded mass of a substance, especially of chewed food or a mouthful of liquid at the moment of swallowing |
| Aspiration | The invasion of a bolus below the level of the true vocal folds |
| Penetration | Entry of material into the larynx, at or above the level of the true vocal folds |
| ONS | ONS are typically used in addition to the normal diet, when diet alone is insufficient to meet daily nutritional requirements |
| PAS | The PAS is an 8-point scale used to categorise swallowing ability and issues related to swallowing safety. |
| Xerostomia | The symptom of dry mouth resulting from reduced or absent saliva flow as a result of a medical condition, a side effect of radiation to the head and neck, or a side effect of a large number of medications |

CLINICAL NUTRITION HIGHLIGHTS

Science supporting better nutrition

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1. Summary

Swallowing is a complex process. When the ability to safely swallow regular liquids is impaired, liquids are thickened to slow flow, in an effort to maintain oral hydration. A combination of bolus properties such as viscosity, yield stress, bolus cohesion and slipperiness facilitate safe passage of the bolus. Studies have demonstrated that these features, examined at various levels of thickness, promote safe swallowing. The literature demonstrates that xanthan gum has features that are most appropriate to facilitate swallowing safety when objectively compared with other thickeners. It is imperative that dysphagia clinicians evaluate individuals with dysphagia to determine the 'thickness dose' that is most appropriate to treat each patient's individual needs. A range of thickness levels are required to meet the variability in dysphagia presentations.

2. Introduction

Dysphagia is the medical term for 'difficulty in swallowing'. In its broadest sense it covers difficulty with managing a bolus from the oral cavity, through the throat (oropharyngeal dysphagia), progressing through to the oesophagus (oesophageal dysphagia). Individuals swallow more than 600 times per day.¹⁻³ Types of boluses include solids (food), liquids, saliva/secretions and medication.

3. The mechanism of deglutition

There are three generally accepted phases of swallowing; the oral phase, pharyngeal phase and oesophageal phase. **Figure 1**. There are subtle differences between the way the body manages the ingestion of solids and liquids; these are described under each of the phases of swallowing. The differentiations are 'philosophical' rather than absolute.

3.1. Swallowing solids

The following considers the scenario of 'a bite of an apple'. **Figure 1**.

A1) As the apple reaches the mouth, the aroma excites the nasal olfactory receptors and there is reflexive secretion of saliva into the oral cavity.

A2) **Mechanoreceptors** in the teeth provide biofeedback as to the bite force necessary to **break the food (bolus) into smaller particles**. The purpose of this particle breakdown is to allow the release of flavour compounds, reduce choking risk and to increase the surface area of the bolus, allowing for easier digestion in the gastrointestinal system.

The bolus is moved from the front of the oral cavity towards the molar teeth closest to the cheeks. The molars provide the surface for **grinding and deforming the bolus**.

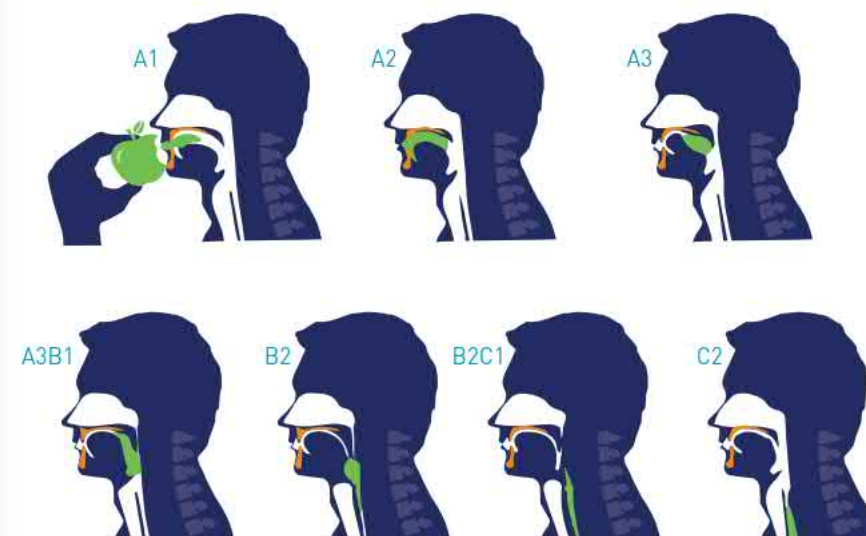


Figure 1. Phases of swallowing

As the food is deformed into smaller particles, it is mixed with saliva and progressively returned to the centre of the tongue where it is collected into a moist "ball" (or bolus).

Saliva aids in adding moisture to soften hard food, and provides a solution for taste molecules to enable the appreciation of sensory qualities, and promote retronasal **appreciation of smell and taste**. This in turn releases more saliva.

A combination of watery and viscous saliva helps to ensure that the **bolus is moist and also slippery**.⁴

Further, **saliva alters the temperature of the bolus**, warming a cold bolus and cooling a hot bolus prior to transporting the bolus to the sensitive mucosa in the pharynx and oesophagus.

During **oral preparation**, the back of the **tongue is raised to provide a barrier to the bolus passing undeformed into the pharynx creating a choking risk**. However, aliquots of chewed food may be passed over the back of the tongue and wait for up to a few seconds at the base of the tongue (valleculae) prior to swallow reflex initiation. As these aliquots are passed to the base of the tongue, **breathing is reflexively paused**, presumably to reduce the likelihood of accidentally inhaling the food particles.⁵⁻⁶

A3) With each closing action of the jaw, the **soft palate swings forward** allowing the aerosols from the partially deformed food fragments as they mix with saliva during chewing to **pass directly to the cribriform plate facilitating flavour** appreciation directly to the brain.

The delicate backward and forward relay between the sensory and motor systems allows the bolus to be expertly deformed into particles of roughly 2-4mm (hard foods) held together by saliva in readiness for swallowing.⁷

The number of chewing strokes required to deform the bolus varies from food type to food type. Hard foods, such as the piece of apple, requires approximately 20 chewing strokes.⁴

A3B1) The **oral phase** lasts for as long as food deformation is needed. Once the bolus particles have been deformed so that **they are sufficiently soft enough to reduce potential damage to the sensitive oral, pharyngeal and oesophageal mucosa** and moist enough to be held together cohesively, the swallow reflex is generated.⁸

During swallow initiation the **lips are closed**, preventing anterior spillage and the jaw is closed bringing **the tongue as close as possible to the hard palate**, providing a **mechanical surface to slide and direct the bolus along**. This process transitions the bolus from the oral phase to the pharyngeal phase. The oral to pharyngeal phase transition also transitions the bolus from voluntary control in the oral cavity to reflexive, involuntary control from the moment the swallow reflex is triggered in the pharynx.

B2) As the swallow reflex is generated it triggers a **series of actions within the pharynx that are designed to protect the airway**.⁹

Constriction of the superior pharyngeal constrictor triggers the middle, then inferior pharyngeal constrictors where the wave is then passed to the oesophagus to create the primary oesophageal wave. Moments before the bolus passes over the base of the tongue, the arytenoid cartilages lurch toward the base of the epiglottis.

The **epiglottis** is a tennis racket shaped cartilage with its base (stalk) nestled in the midline of the thyroid cartilage, one of the key structures of the larynx.

The **base of the tongue** connects via muscular attachments with the hyoid bone. The hyoid bone sits in the neck, under the floor of the mouth.

The **hyoid bone** is in turn connected to cartilages of the larynx and also the muscles of the pharynx, creating a unique pulley system. The "anatomical pulley system" allows the entrance to the airway (larynx) to be physically moved upwards and forwards under the protection of the base of the tongue; away from the passing bolus.

The **pharynx** is physically shortened during this process creating a shorter passage for the bolus.

As the **larynx** is lifted, the movement allows the top-heavy epiglottis to fold over the entrance to the airway.

Beneath the epiglottis, the **vocal folds** come together as a further physical barrier to the opening of the airway and breathing momentarily stops (~ 1 sec). Although the epiglottis forms a physical barrier over the airway entrance it is not a perfect seal; it is not like a cork in a bottle. In fact, its presence is much like rock in a stream, creating a mechanism to alter the direction of flow so that the bolus travels through pockets (pyriform sinuses) around either side of the larynx.

B2C1) During **hyolaryngeal movement**, the unique muscular connections between the larynx and the opening to the oesophagus trigger relaxation of the valve that separates the **pharynx** from the oesophagus, allowing the upper oesophageal sphincter (UES) to open and for the bolus to pass through the pharynx and into the **oesophagus**.

A **series of peristaltic waves** are generated within the oesophagus to progress the bolus in a rhythmic fashion towards the lower oesophageal sphincter; the gateway to the stomach. The triggering of the primary peristaltic wave also triggers relaxation of the lower oesophageal sphincter, the valve between the oesophagus and the stomach, easing passage of the bolus into the stomach for further processing. For solid foods, secondary peristaltic actions are triggered by the presence of the bolus within the oesophagus helping to propel it towards the stomach.

C2) The oesophageal phase typically lasts 4-8 secs for solids.¹⁰

Efficient bolus passage

For the passage of the bolus to be efficient there are a series of actions that need to occur almost simultaneously. The swallowing system can be likened to a mechanical system. High resolution manometry (HRM) demonstrates that the bolus is subjected to variable pressures as it moves through the mouth, pharynx and oesophagus.

Closure of the lips during swallowing creates a sealed chamber anteriorly.

The **tongue provides the propulsion** for the bolus head to pass deep into the pharynx. Tongue base pressures acting on the bolus are in the order of 214 mmHg for healthy people.¹¹ The tongue base meets the pharyngeal constrictors that, as their name suggests, squeeze in a circular fashion to ensure the tail of the bolus is cleared away from the airway.

The **soft palate closes as the swallow reflex is generated**, ensuring that neither the bolus, nor the pressure generated by the tongue can be lost through that valve. In fact, the maximum pressure generated at the soft palate (velopharynx) is approximately 221 mmHg in healthy people.¹²

The **airway closes with a pause to breathing** reducing the likelihood of drawing the bolus towards its entrance.

The **upper oesophageal sphincter relaxes** below the resting pressure of 96 mmHg and opens for about 0.68 secs to accept both the bolus and the pressure driving it.

Bolus propulsion is aligned to UES opening and relaxation.

The triggering of the **primary peristaltic waves** and **vacuum** created with a closed system allows the bolus to be carried away from the pharynx and pulled towards the stomach.

Once the UES has closed, the 'danger' of the bolus has passed.

The airway re-opens, the tongue, jaw and pharynx return to resting position while the soft palate relaxes, facilitating nasal breathing.

3.2. Swallowing liquids

The following considers the scenario of a mouthful of water as it is taken from a glass. The volume taken depends on the stature of the person, with taller individuals taking a larger mouthful than smaller statured people (average 20-25 mL). **Figure 1**.

A1 A2) The **lips provide a seal** to ensure that liquid passes into the oral cavity. In the case of liquids, the tongue controls and directs the liquid bolus.

A3) The **back of the tongue** is raised to protect the airway, as for the example of solid foods above. The body of the tongue cups to accommodate the bolus.

A3B1) **Sensory receptors** detect the presence of the bolus and, working in tandem with motor receptors, the same sequence of events listed above is set into motion. Again, a small amount of the bolus may transiently move to the spaces at the base of the tongue just prior to swallow reflex initiation.

B2) The **lowering of the epiglottis** causes the bolus to split and travel on either side of the larynx through the pyriform sinuses to the opening of the oesophagus. In contrast to solids, the oral phase for liquids is very fast at approximately 1 second.

B2C1) The **pharyngeal phase** is the same for solids and liquids with a duration of 1 second allowing passage of the bolus while respiration is momentarily ceased.

C2) Travel time through the **oesophagus** is 1-2 secs for liquids.¹⁰ Unlike solid food, the primary peristaltic wave is sufficient to facilitate passage of the liquid bolus into the stomach without further peristaltic waves being generated.

Healthy individuals sometimes segment a single mouthful into smaller aliquots for swallowing. They do this by holding a portion of the bolus towards the front of the mouth while swallowing the remainder of the bolus. This, often unconscious strategy, may be used as a safety mechanism when the initial mouthful is too large, too hot or too cold to be swallowed as a single unit. It may also be used to prolong oral exposure if the taste of the liquid is pleasant (e.g. wine).

4. Dysphagia to solids and liquids

The mechanisms and repercussions of dysphagia for solids and liquids are quite different.

Dysphagia for liquids occurs when the liquid is lost from the front of the mouth, and more importantly from the back of the oral cavity where there is a **high risk for the liquid to enter the larynx; the gateway to the lungs**. Difficulty controlling the flow of liquids can result in a fear of swallowing. Frequent coughing or choking episodes can cause the person to avoid drinking, therefore taking insufficient liquids to maintain adequate hydration. It is just as dangerous when the person has no awareness that aspiration is occurring, where the liquid enters the airway and lungs.

Dysphagia for liquids
can result in **aspiration** where the liquid enters the airway and lungs

Dysphagia for solids can result in **asphyxiation** with food pieces

Dysphagia for solids can result in **asphyxiation** with food pieces physically blocking the airway and the preventing the ability to breathe.

Both types of dysphagia can cause **serious illness** such as **malnutrition, dehydration** and also complications such as life-threatening aspiration pneumonia, and/or choking, resulting in **death**.

Where there is a significant **loss of muscle mass and function**, it is known as **sarcopenia**; this is a hallmark

feature of frailty.¹² Frailty results in an age-associated decline in reserve and function and is characterised by low grip strength, low energy, slow walking speed, low physical activity and unintentional weight loss. Whilst sarcopenia is more commonly associated with skeletal muscles for walking and hand grip, muscle wasting is also seen in the muscles associated with eating and swallowing. A study of **frail elderly** patients showed that more than **two thirds presented with oropharyngeal residue, more than half presented with penetration** of the bolus above the opening of the airway and **17% demonstrated tracheobronchial aspiration or airway invasion**. Impaired tongue propulsion and delayed movement of the hyolaryngeal muscle pulley system complex was linked to oropharyngeal residue across liquid thickness levels. These features were not evident in healthy participants.¹³ Changes in muscle integrity associated with sarcopenia could contribute to reduced tongue propulsion and delayed hyolaryngeal excursion noted in these elders. At one-year follow up, mortality rates were significantly higher in frail elderly patients (56% vs. 15%) with impaired swallowing safety or swallowing efficiency.

FRAIL ELDERLY PATIENTS:
66% oropharyngeal residue
>50% penetration
17% tracheobronchial aspiration or airway invasion
56% on-year mortality

For both solids and liquids, **safe swallowing relies:**

- On the integrity of sensory and motor systems within the oral cavity, pharynx and larynx
- On the lubrication and integrity of the mucosa and oropharyngeal structures

4.1. Swallowing problems arising from reduced integrity of the sensory and motor systems

4.1.1. Problems with the sensory system

Problems with the sensory system, such as that which might occur **following stroke, head and neck cancer**, or in the **later stages of dementia** can cause the food or liquid to be poorly sensed or perceived. Reduced ability to sense the bolus means that its

movement within the oral cavity cannot be tracked and therefore cannot be well controlled. Clinical studies evaluating tongue pressure show significantly reduced tongue-to-palate pressure and different tongue pressure patterns in individuals with dysphagia as a result of stroke.¹⁴ Poor sensation of the bolus can result in misperceptions of bolus size, or readiness for swallowing. It can also cause poor timing for swallow reflex initiation if sensory loss is uneven within the oral cavity. This may result in the bolus falling into the pharynx and larynx before the safety mechanisms that normally protect it are in place. As noted in **Section 3**, these safety mechanisms include:

- Physical barriers, such as closure of the vocal folds and deflection of the epiglottis over the opening of the larynx
- System optimisation for bolus propulsion including tongue driving force to generate bolus velocity through the pharynx and closure of anatomical valves to improve the effectiveness of bolus propulsion
- Cessation of respiration to avoid pulling the bolus towards the airway while it is moving; and
- Opening and timely closure of the upper oesophageal sphincter (UES) to allow bolus entry, and then containment in the oesophagus for further propulsion to the stomach.

As noted above, the bolus is subject to a variety of pressures as it travels through the oral cavity, pharynx and oesophagus. The pressures, and also the velocity of the bolus, provide proxy measures of the strength and efficiency of bolus movement during swallowing. Lower pressure scores are associated with abnormal swallowing function. Specifically, HR manometry studies have shown that individuals with dysphagia of mixed aetiology demonstrated significantly lower pressures generated at key 'anatomical valves' of the soft palate and tongue base, with sig-

nificantly lower UES resting pressure and ability to sustain the resting pressure (0.49 secs) compared with the values for healthy individuals (0.68 sec). Pressures are shown in **Figure 2**.¹¹

The bolus tail is cleared by action of the squeezing pharyngeal constrictors. Deficiencies in this area are associated with residue remaining in the pharynx after the swallow. In a group of individuals with dysphagia, lower mean pharyngeal contractile interval scores have been significantly associated with greater swallowing impairment as per **Figure 3**.¹⁵



Figure 3. Mean pharyngeal contractile interval scores associated with swallowing impairment¹⁵

4.1.2. Problems with the motor system

Problems with the motor system, again as a result of **neurological damage to nerves and/or muscles**, or **structural changes associated with surgery** (e.g. head and neck cancer) **significantly impact the ability to move the food or liquid for chewing and swallowing**. This may result in:

- Difficulty moving the food pieces to the molar region for chewing,
- Insufficient bite force, leaving the bolus poorly deformed; and/or
- Poor control of the direction and speed of movement of the bolus as it nears the pharynx.

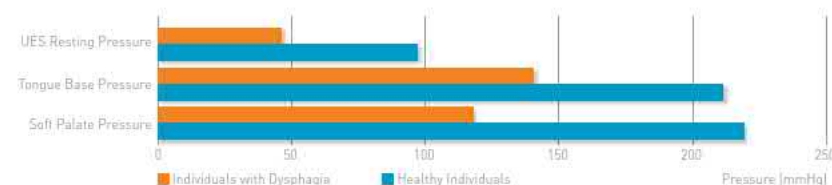


Figure 2. Pressures generated during swallowing: Comparison between healthy individuals and individuals with dysphagia¹¹

Poorly deformed food may result in the person swallowing chunks that are too large and could cause a **choking risk**. Where the sensory system remains intact, but the motor system is faulty, individuals can sense that a bolus has been incompletely prepared but are unable to action that feedback. This can result in insufficient food being consumed. An example of this type of problem is Motor Neurone Disease, where fatigue is associated with attempts to prepare the bolus in line with feedback from the sensory system but there is a lack of motor action to respond to the sensory feedback. The food may fracture with a loss of momentum if it is not propelled swiftly. The fractured pieces may then collect at the base of the tongue (valleculae) or in the pockets on either side of the larynx (pyriform sinus).¹⁴ In a **worst-case scenario, choking and asphyxiation can occur with solid food**.

With liquids, **poor motor ability** may result in the **liquid escaping from the lips and/or falling over the back of the tongue into the open airway**. Healthy people with an intact sensory system will cough to expel liquid that has entered or attempted to enter the upper airway. However, sensory loss is common post-stroke, and although liquid enters the airway, a protective cough is not triggered during the airway invasion (aspiration). If liquid is aspirated often enough, or in sufficient quantities, together with other predisposing factors related to oral hygiene and integrity of the immune system, conditions may arise for life threatening **aspiration pneumonia (AP)** to develop. The bolus might also be propelled with a low velocity such that remnants are not adequately cleared from the pharynx and remain in the valleculae or pyriform sinus waiting to be cleared with a further clearing swallow.¹⁷

Although sensory and motor deficits have been described in isolation above, there are conditions where both sensory and motor deficits combine to increase the severity of dysphagia.

4.2. Changes to salivary lubrication of the oral cavity

The final element that must be considered that impacts dysphagia is the **lubrication of the oral cavity**. The oral, pharyngeal and oesophageal mucosa is typically bathed in saliva that protects and keeps the mucosa moist and slippery.

Saliva is made up of both a watery and viscous, but slippery component (mucin). Particularly for food,

the coating of the bolus in the slippery mucins of saliva allows it to slide along the surface of the moist and slippery mucosal structures. **Conditions that reduce saliva flow or change the saliva composition** change the boundary conditions for the bolus, and provide friction, **making it difficult to slide the bolus through the oral cavity and through the pharynx**.¹⁸ Think of trying to roll a sticky ball along a sticky surface rather than a slippery ball gliding along a slippery surface.

The tongue must work harder to propel the bolus out of the mouth and into the pharynx. The pharyngeal constrictors must work harder and for longer to squeeze the tail of the bolus through the pharynx. Due to the sticky nature of the mucosa, the bolus may fracture and stick at the base of the tongue (valleculae) or in the pockets on either side of the larynx (pyriform sinus) requiring additional swallows to clear the residue. Mucosal stickiness may also extend into the oesophagus, making it difficult for the bolus to pass through the oesophagus to the stomach.

Dry mouth (xerostomia) is a feature of the immune disease Sjogren's Syndrome and is a common side effect of radiation to the head and neck. Xerostomia is also a common side effect of many medications. Given that the average elderly person consumes 6-8 medications daily, their risk for dry mouth is increased.¹⁹

5. Main physical and rheological properties of bolus that facilitate swallowing function

The bolus can be solid, liquid or secretory in nature. The ideal bolus is soft, smooth or homogenous in texture.²⁰⁻²² It holds together to **allow efficient transport through the mouth thereby avoiding particle loss during transfer from the front of the mouth to the back of the mouth where the swallowing reflex is triggered**.

The bolus is also slippery, allowing it to glide along the oral, pharyngeal and oesophageal mucosal surfaces. Factors that increase softness allowing malleability, smoothness and homogeneity of texture include chewing and the addition of saliva.

Some foods have a high-water content, while others increase their water content by supplementation with saliva released during chewing and oral preparation. The moisture content of the 'ready-to-swallow bolus' is relatively constant. This is regardless of the

initial state or texture of the food, demonstrating the importance of the sensory system to perceive this feature as well as the importance of the motor system for bolus preparation.²⁰⁻²⁴ **The bolus must also have sufficient weight, or density, and cohesion** for it to be sensed by the oral cavity and interpreted by the brain as a substance that is suitable for swallowing.

For a person with swallowing difficulties,

- **What features of the bolus can be manipulated to improve swallowing safety and swallowing efficiency where the anatomical or physiological system has become impaired?**

The liquid bolus is fragile when being transported. When propelled with sufficient force, a liquid bolus is able to travel as a unit. In part this may be aided by hydrogen bonds creating cohesive forces within the liquid. Alternatively, drawing on fluid mechanics, when there is sufficient pressure behind the flow, and it becomes fully developed, the pressure allows it to keep its form, like the spray from a high pressure 'jet-like' garden hose. Where there is **insufficient bolus propulsion and pressure** however, **the bolus will spread in many directions within the oral cavity**. A subtle movement of the tongue, or an incomplete lip closure will see the bolus escaping from the lips, pooling in the cheeks (buccal sulci) or disappearing over the base of the tongue and into the pharynx at a speed dictated by gravity.

- How does one slow the bolus to allow weak or poorly timed muscles to control a fast-moving liquid?

- How does one provide sensation to alert the body that a bolus is present within the oral cavity where oral sensation is diminished?
- How does one provide a smooth, homogenous bolus where the oral system is unable to create one by chewing and/or bolus manipulation?
- How does one provide a wet and slippery bolus where the body is unable to generate this by producing enough saliva to make the bolus and the mucosa slippery to aid bolus transport?

Thickening of a liquid address many of the questions raised. It will **reduce the speed of movement**, and at that same time the **thick nature of the liquid can be more easily 'sensed' within the oral cavity than a thin liquid**. Liquids such as water, milk, juice, tea, coffee, and wine for example, are classified as 'thin' liquids. They flow freely, quickly and unpredictably.

Thickened liquids **allow the body more time to respond, creating a compensatory mechanism to assist airway protection**. The concept of thickness is known as 'viscosity'.

The addition of thickening agents to regular liquids to increase their viscosity provides a reasonable hypothesis to address the challenges raised by dysphagia for liquids. The ideal attributes of the bolus and their impact on the oral and pharyngeal phases of swallowing are shown in **Figure 4**.

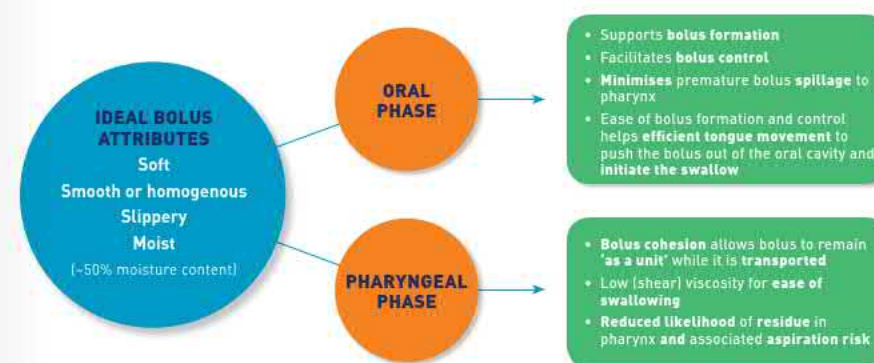


Figure 4. Ideal attributes of the bolus and their impact on the oral and pharyngeal phases of swallowing

6. Properties of thickeners and their mechanism of action

Liquids can subjectively be described as 'thin', like water, or 'thick', like a thick-shake. Rheology is the study of the deformation and flow of matter. Rheologically, all fluids are described in terms of (a) viscosity, (b) density, and (c) yield stress. Although these features of a bolus are most commonly described, there may be other features that are relevant to products designed to aid swallowing for people with dysphagia.

6.1. Viscosity

When objectively describing the 'thickness' of liquids this is a discussion of 'viscosity'. **Viscosity is the resistance of a substance to flow under an applied force.**

Liquids like water do not have much resistance to flow and are, therefore, classified as 'low viscosity'. It takes little effort to stir water with a spoon.

Liquids like molasses or tomato sauce (ketchup) have very slow flow rates and consequently a 'high viscosity'. This time the effort to stir is much greater due to the internal structure of the liquid.

The **unit of measurement for viscosity** in the International System of Units (SI) is pascal-seconds, although it is more commonly reported in the dysphagia literature as **millipascal-seconds (mPa.s)**. Viscosity may also be reported in the unit **Centipoise (cP)**, where 1 cP = 1 mPa.s.

Viscosity can be measured by apparatus that vary in design and are chosen as 'fit for purpose'

depending on the nature of the sample to be tested. **Viscometers** or **rheometers** are generally rotational or capillary style instruments and are used for time-dependent measurements.²⁷ **Figure 5**. Parallel plate and cone and plate geometries are often reported for measurement of viscosity in the Literature. These devices are most often found in laboratories or in universities and are rarely found in health settings.

When measured using a rheometer, **water** at 20°C, measured at a shear rate of 50 s⁻¹, has a viscosity of 1.0 mPa.s.²⁸ In contrast, **honey** has a viscosity of 10,000 mPa.s, and the **tomato sauce (ketchup)** mentioned earlier has a viscosity of 50,000 mPa.s. The larger the number, the thicker the substance. Although water and honey have very different thicknesses, they are both Newtonian fluids.

Newtonian fluids can be described as fluids where the force required to make the fluid flow is directly proportional to the resulting amount of flow.²⁸ The internal structure of the hydrogen and oxygen molecules within the liquid makes it easy for them to slide over one another. Not all liquids, however, are Newtonian in nature.

For non-Newtonian fluids the viscosity varies with the force being applied to the fluid (or rate of strain). In practical terms, if one stirs thickened liquids slowly, they appear thick. However, the more vigorously one stirs thickened fluids, the thinner they become. In measurement then, we need to know how much strain is being applied to the fluid, or 'how vigorous the stirring is', to be able to anchor and describe the viscosity in a meaningful way. Non-Newtonian fluids can be further sub-categorized. Thickened liquids used in dysphagia management can be 'shear thinning', meaning that the fluid's resistance to flow decreases with increasing rate of shear. That is, they become thinner when sheared ('stirred' or moved) quickly.

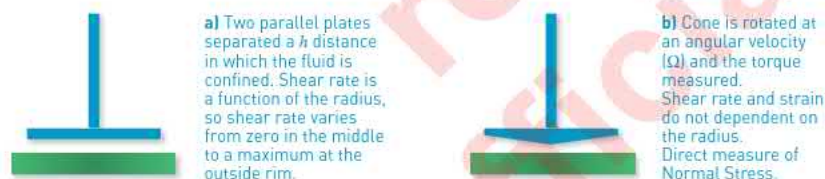


Figure 5. 5a. Schematic of parallel plate geometry and 5b. Schematic of cone and plate geometry for measuring viscosity

Water and honey are both Newtonian fluids

Food items tomato sauce (ketchup) and mayonnaise, and thickened liquids used in dysphagia management, are non-Newtonian fluids

To accurately appreciate the viscosity of thickened liquids, it is critical that the shear rate being applied to the liquid is known. This is particularly important for understanding the viscosity of non-Newtonian liquids. As noted above, apply a vigorous or fast rate of strain, and the liquid becomes thinner; apply a slower rate of strain and the liquid maintains its thickness level.

In the oral cavity as we savour a spoonful of chocolate pudding there is little tongue movement, however, a pudding that has an unpleasant flavour

may be moved very quickly through the oral cavity and into the pharynx. Thus, the tongue plays a critical role in changing the shear rate, or how vigorously the bolus moves in the mouth, and ejection from the oral cavity into the pharynx. The pharyngeal constrictors also play a role in sweeping the tail of the bolus through the pharynx, applying a further shear rate.

Dating back to the early 1990's shear rates were reported for swallowing in the range of 1-100 s⁻¹ with an average value of 50 s⁻¹.²⁹⁻³⁰ By way of example 50 s⁻¹ refers to a change in velocity from 0 to 50mm/sec over a distance of 1mm.³¹ While a Newtonian fluid such as water has a constant viscosity of 1 mPa.s regardless of whether it is sheared at 50 s⁻¹ or 100 s⁻¹, for non-Newtonian liquids the viscosity values measured at 50 s⁻¹ vs. 100 s⁻¹ are very different. As shown in **Figure 6** below, the samples measured at a shear rate of 50 s⁻¹ are thicker than when they are measured at a faster shear rate of 100 s⁻¹.

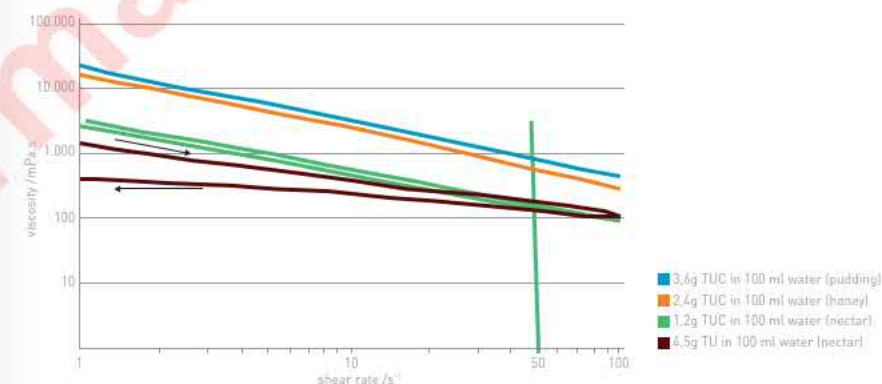


Figure 6. Viscosity of samples of thickened liquids at various shear rates, with a focus on viscosity (thickness) at 50 s⁻¹. Abbreviations: TUC, Resource® ThickenUp Clear; TU, Resource® ThickenUp. Source: Popa Nita et al, 2013³¹

Stokes *et al.*³² challenge that although it may be possible to create thickened liquids that have a similar viscosity at 50 s⁻¹ the viscosity above and below this shear rate is far more difficult to control due to properties such as elasticity. In fact, Popa Nita *et al.*³¹ clearly demonstrate this point showing that for shear rates at and above 50 s⁻¹ that there is little difference in the apparent viscosity of Varibar® Honey and Pudding liquids. Although for healthy people an oral shear rate of 50-100 s⁻¹ has been put forward for industry standard testing, the oral shear rates of

individuals with dysphagia are unknown. With poor tongue strength and coordination, that is a common feature of oral dysphagia, it would be reasonable to suggest that the oral shear rate for individuals with dysphagia would be far less than 50 s⁻¹.

Why is shear rate important?

The variability in bolus speed and pressure during the swallowing process means that the bolus is sub-

jected to a range of stresses that differ between the oral cavity, the pharynx and the oesophagus. If we accept that the oral shear rate may be 50 s^{-1} , the pharyngeal shear rate has been proposed to vary from 120 s^{-1} within the pharynx above the larynx and approximately 990 s^{-1} within the pharynx below the larynx.²³ The results reported were based on a very small sample size of three individuals. This means that a thick liquid may start as one thickness in the oral cavity, but as it is swallowed, it may become thinner and more stretched due to muscular forces acting upon it, like a 'mechanical insult'. Pressure changes from ~ 200 mmHg at the tongue base increasing to 300 mmHg in the pharynx means that the bolus will be stretched and become thinner as it passes through the pharynx. Warming of the bolus to equilibrate it towards body temperature as it passes through the oral cavity and pharynx may also improve bolus malleability and swallowing ease.

The anatomical design of the pharynx and physiological process of swallowing promotes bolus flow safely around the larynx helping to compensate for thinning of the bolus that occurs in the pharyngeal phase during swallowing.³⁴ For individuals with dysphagia, the degree of tongue propulsion and pharyngeal action to squeeze the tail of the bolus past the larynx will thin the bolus as compared to its original thickness in the mouth, however it will not be the same as the deformation produced by the pharyngeal pressures of a healthy individual. Further if there is **no propul-**

sion and the bolus falls over the base of the tongue at a speed dictated by gravity, this is faster than if the bolus is controlled during swallowing.³⁴

Thin liquids move rapidly and can spill out of the mouth and into the throat.

The **thickness of the bolus** has an impact on its velocity as it travels through the pharynx. In a study of healthy individuals of different ages, swallowing liquids of different thickness levels, differences in bolus velocity were identified.³⁵ Of interest gender and age differences were noted. Age-related changes were noted for males such that the bolus tail velocity decreased as males became older. However, for females there was a constant average swallowing velocity regardless of age. When the fluid thickness reached 496 mPa.s or greater, the effect of velocity was reduced regardless of gender and averaged at 85–100 mm/s as per Figure 7.

Thickness of the bolus (viscosity) has an impact on its velocity, it moves more slowly through the oral cavity and pharynx than thin liquids resulting in safer swallowing due to a lower incidence of aspiration and infiltration into the larynx.

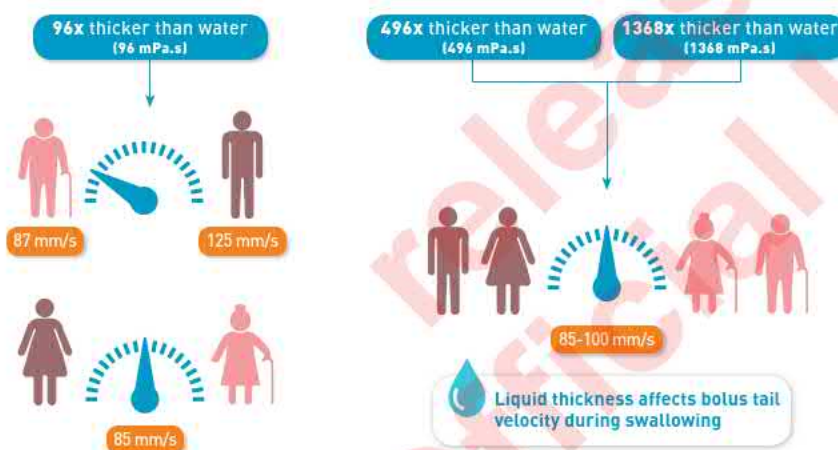


Figure 7. Liquid thickness affects bolus tail velocity during swallowing

Fluid thickness also affects **pharyngeal pressures** such that higher pharyngeal contractile integral pressures have been recorded for pudding thick liquids (>1750 mPa.s) compared with thin liquids for healthy individuals (300 mmHg.cm.s vs. 223 mmHg.cm.s).¹⁵ Pharyngeal pressures of 188 mmHg.cm.s, however, are associated with swallowing impairment, suggesting that the pharyngeal shear rate for people with dysphagia is less than that for people with intact pharyngeal function.

Whilst the viscosity of a liquid provides us with useful information, it does not provide us with a complete understanding of the structure of the fluid.

As an analogy, imagine that we know the weight of an individual. For argument's sake the adult person weighs 55 kg. However, we need much more information before we can determine whether this person's weight should be cause for concern. If the person were male, 55 kg and 190 cm in height, then we would have grave concerns for his physical health, compared to the same weight of a female of 159 cm height. A similar situation occurs with thickened fluids. To have just the viscosity information alone is insufficient. To truly understand the behaviour of thickened fluids we need to consider the material properties of density and yield stress to increase our understanding.

6.2.Density

Density of a fluid is mass per unit volume and most closely equates with the weight of the fluid.

One tends not to think of fluids as having characteristics that make them 'heavy' or 'light', however, this aspect of a fluid's characteristics becomes important when considering the addition of barium to fluids, as is the requirement for radiographic assessment of swallowing (modified barium swallow or videofluoroscopy).

Barium has previously been reported to have high- or low-density preparations.³⁴ High-density barium changes the physiological parameters of swallowing such that oral transit time and pharyngeal clearance time is longer than for low-density barium preparations. Increased density of barium-enriched thickened fluids when compared with unenriched thickened fluids has also been reported in the literature.³⁷ Further, two liquids may have the same viscosity but have different densities. For example, thickened infant formula has a density of 0.91 g/cm^3

while liquid barium has a density of 1.62 g/cm^3 , despite both liquids being of comparable viscosity.³⁴

A fluid that has a **higher density will require more force to generate movement**. Nicosia & Robbins³⁸ reported that density is a major determinant of fluid ejection from the oral cavity for low viscosity (*i.e.* thinner) liquids, while for thick fluids (1000 mPa.s and greater), viscosity is more important. Between the values of 100–1,000 mPa.s, both viscosity and density have been found to affect ejection time in a mathematical model based on Newtonian fluids.³⁸ Density of a fluid is usually measured by accurately weighing the fluid of interest in a graduated cylinder of known volume and is reported in g/cm^3 .

6.3.Yield Stress

Yield stress relates to the **composition of the fluid**. A fluid that has a 'yield stress' is one where an inherent structure of the fluid must be broken down to allow the fluid to flow. **Yield stress is defined as the stress above which flow occurs.**

Fluids that have a yield stress are usually a particle-filled fluid or a gel.

*Consider a single billiard ball and then a group of billiard balls packed close together. There is minimal effort required to push the single ball, however, the more balls that are added to the group, there is an increase in effort required to move the balls as a group. This is because you first need to overcome the packing arrangement (yield stress) before flow (or in this case movement) will occur.*³⁹

Steele and Van Lieshout⁴⁰ reported the yield stress of honey-thick apple juice at 1.42 Pa, whilst its barium counterpart showed a yield stress of 2.1 Pa; not quite double the magnitude. In this instance, more tongue force could be anticipated in order to make the bolus flow. The thicker the fluid, the greater will be its resistance to shear stress. Yield stress is determined from plots of viscosity versus shear stress as measured using a viscometer or rheometer. If viscosity is seen to approach infinity as shear stress approaches zero, then a yield stress is said to be present. Yield stress is measured in Pascals (Pa).

Whilst all three elements of viscosity, density and yield stress most accurately describe any given liquid, as fluids become thicker, the importance shifts to viscosity, with density reportedly playing a limited role.

There are other emerging bolus parameters that also influence swallowing safety. These include cohesion, adhesion, surface tension and perhaps others. These parameters relate to textural and sensory features such as stickiness, slipperiness and fracturability. Evaluation of cohesion or bolus elasticity is emerging as a critical feature of the swallow-safe bolus.⁴¹⁻⁴²

7. Effect of bolus viscosity on swallowing safety and swallowing efficiency in oropharyngeal dysphagia (OD) patients

7.1. Effect of viscosity on the oral and pharyngeal stages of swallowing

To determine the effectiveness of thickened liquids as an aid to swallowing safety and swallowing efficiency there are a number of parameters that clinicians review. These are summarised in Table 1.

| Parameter of the bolus or physiology measured during radiographic swallowing assessment | Impact on swallowing safety |
|---|---|
| The size of the bolus naturally selected | Natural selection of a small to moderate bolus as opposed to a large bolus demonstrates an ability to 'sense' the presence and size of the bolus |
| Segmentation of the bolus within the oral cavity | The decision to segment a single bolus into smaller boluses for swallowing indicates the ability to 'sense of the size of the bolus' and choose to hold some of the bolus in the mouth and progressively swallow small portions until the entire mouthful has been cleared |
| Efficiency of oral transit time | A bolus that moves efficiently through the oral cavity is less likely to pool in the mouth and mix with saliva, thinning the solution and making it more difficult to control |
| Efficacy of oral transit | Well-executed oral transport leaves minimal residue requiring fewer clearing swallows |
| Hyoid movement | Good hyoid movement is associated with well-functioning pulley like connections to enable opening of the upper oesophageal sphincter, allowing the bolus to pass out of the pharynx and into the oesophagus |
| Efficiency of pharyngeal transit time | A bolus that moves efficiently through the pharynx reduces the amount of time the person needs to hold their breath (apnoea) to protect the airway. Well executed pharyngeal transport leaves minimal residue in the pharynx that will require clearing swallows to allow breathing to resume without risk of drawing residue into the airway |
| Accuracy of pharyngeal transit (presence or absence of aspiration) | Accurate pharyngeal transit results in the bolus being delivered to the oesophagus, rather than the airway |
| Breath-holding duration while the bolus is passing through the pharynx (apnoea) | Ability to breath hold for the entirety of the time the bolus is in the pharynx and in proximity to the airway entrance is a protective feature |
| Total swallow duration | Short swallow duration and long swallow duration can both be positive features. Their categorisation needs to be viewed in conjunction with whether the speed of the swallowing event resulted in aspiration or avoided aspiration |

Table 1. Bolus parameters observed during radiographic assessment of swallowing and its impact on swallowing safety and swallowing efficiency?

7.2. Effect of viscosity on swallowing safety and swallowing efficiency

Thick fluids show a number of physiological changes to swallowing biomechanics that assist with safer swallowing.

For individuals with dysphagia, swallowing thick fluids results in smaller sip sizes,⁴⁰ demonstrating an improved ability to sense the bolus with a smaller volume delivered to the airway if aspiration were to occur.

Physiologically, swallowing thick fluids have been found to result in longer periods of breath-holding during the swallow (apnoea), and an exhalation breath after the swallow, which are both part of the natural airway protection mechanism.⁴³ Chifishman & Sonies,⁴⁴ also found that swallowing of thickened fluids shows longer periods of pre-swallow hyoid gestures than thin fluids. This action assists in opening the upper oesophageal sphincter via the hyolaryngeal pulley-like excursion, facilitating passage of the bolus away from the pharynx and into

the oesophagus; a protective gesture. Maximum oral muscular activity has been found to increase as liquids and pastes become progressively thicker.⁴⁵ Total swallow duration increases from liquids to thin pastes (e.g. apple sauce) to thick pastes (e.g. cheese spread or peanut butter). The evidence related to the number of different levels of thickened fluids demonstrates benefits related to thin fluids vs. paste thickness.⁴⁵⁻⁴⁶

Two recent systematic reviews of the literature both confirm the benefit of thick fluids in reducing aspiration.⁴⁷⁻⁴⁸ Specifically, the reviews found that thickened liquids increase swallowing safety by reducing the likelihood of penetration and aspiration. Figure 8. This is in agreement with the work of Zhu *et al.*³⁴ who described using fluid mechanics and videofluoroscopy that increasing liquid viscosity changes flow through the pharynx from fast gravity driven flow to slow, displacement flow, and a consequent reduction in bolus velocity.

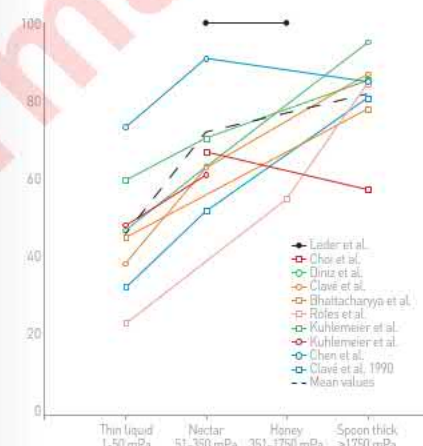


Figure 8. Benefit of thick fluids in reducing aspiration⁴⁸

However, both systematic reviews also found that thicker consistencies, (especially pudding thick) regardless of thickening agent were associated with an increase in residue in the pharynx after the swallow, potentially resulting in post-swallow airway invasion.⁴⁸ Moreover, Bolivar-Prados *et al.*⁴⁹ and Vilardell *et al.*⁵⁰ in recent studies have shown, the use of xanthan gum-based thickening agents

improve safety of swallowing without increasing pharyngeal residue.

Robbins *et al.*⁵¹ demonstrated that for individuals with dementia in long-term care settings, there is a two-fold increase in the incidence of pneumonia for individuals provided with liquids thickened to 3000 mPa.s as opposed to liquids thickened to 300 mPa.s

Bisch *et al.*⁴⁶ examined differences in swallowing physiology as a function of viscosity for small samples of healthy individuals and those following stroke or neurological impairment. The increase in viscosity from a thin liquid to a pudding consistency resulted in safer swallowing for the stroke population due to improved timeliness of swallow reflex initiation. For the neurologically impaired group, benefits to safer swallowing were also demonstrated with a pudding consistency. For example: slowed bolus transport, improved timeliness of swallow reflex initiation, earlier airway protection, faster pharyngeal processing and longer opening of the UES, allowing a better chance of clearing the bolus through the pharynx and into the oesophagus.

Raut *et al.*⁵² found that with increased viscosity, the hypopharynx contracts harder and for longer to protect the pharynx. This pattern fits with the recommendation of speech pathologists to recommend the use of thickened fluids to protect the airway. However, they caution that for 'weak' and sarcopaenic patients or those with pharyngeal phase dysfunction, the ability to swallow thick and viscous substances is impaired due to an inability to produce the pressures at the tongue and pharynx required to move the bolus. Moreover Newman *et al.* found that thickened liquids induced increased tongue pressure patterns during swallowing and a reduced compliance with consumption as thickness increased.

Increased viscosity does not solely explain improved swallowing safety. A 2014 prospective, double-blind study investigating the effects of viscosity on aspiration in patients with dysphagia, found that while both starch and gum-based thickeners reduced aspiration events, the gum-thickened liquids appeared to be more effective compared to water, despite being a lower viscosity than the starch-based thickened liquid.⁵³ Properties other than viscosity provide textural and sensory cues that may be protective for swallowing function. The impact of being able to provide improved swallowing safety at a lower viscosity level is that compliance with consuming thickened liquids, and therefore hydration, is better with thinner liquids.

Clinical practice guidelines for the management of dysphagia issued by several associations, including the European Society for Swallowing Disorders (ESSD)⁵⁴, the European Union Geriatric Medicine Society (EUGMS)⁵⁵, the European Society for Clinical Nutrition and Metabolism (ESPEN)⁵⁶⁻⁵⁷, World Gastroenterology Organization global guidelines⁵⁸, the

National Institute for Health and Care Excellence (NICE)⁵⁹, the British Dietetic Association⁶⁰, and the Scottish Intercollegiate Guidelines Network⁶¹, recommend an intervention with dietary modifications including liquids of appropriate viscosity/consistency such as thickened fluids with the aim of reducing the risk of aspiration pneumonia. **Table 2.**

| Clinical practice guideline | Key recommendations |
|--|---|
| European Society for Swallowing Disorders Position Statements, 2012 ⁵⁴ | <ul style="list-style-type: none"> Evidence-based individualized treatments include bolus texture modifications and postural adjustments alongside stimulation-based therapies – all of which require further cost-benefit analysis. A variety of texture modified foods/modified fluid consistencies should be offered/provided to promote enjoyment and encourage intake. |
| European Society for Swallowing Disorders – European Union Geriatric Medicine Society white paper: oropharyngeal dysphagia as a geriatric syndrome, 2016 ⁵⁵ | <ul style="list-style-type: none"> Suggest guidelines published by the British Dietetic Association and the Royal College of Speech and Language Therapists to provide detail on the kinds and textures of alimentary products needed by patients with oropharyngeal dysphagia. Patients following modified texture diets should have their swallowing and nutritional status regularly assessed, after the first week and then every 2-3 months for the first year and then every 6 months. |
| European Society for Clinical Nutrition and Metabolism guideline clinical nutrition in neurology, 2018 ⁵⁶ | <ul style="list-style-type: none"> Liquid thickening should be applied in patients with oropharyngeal dysphagia aspirating on liquids. Liquid intake needs to be closely monitored since there is a high risk of insufficient oral intake. Recommendation A (strong consensus: 100%). To improve patients' compliance different types of thickening agents should be offered for choice. GPP recommendation (strong consensus: 95%). Thickened liquids should be used in persons with chronic dysphagia to enhance nutritional status – Recommendation B (strong consensus: 100%). |
| ESPEN guideline in geriatrics, 2019 ⁵⁷ | <ul style="list-style-type: none"> Texture of food and drinks that can be swallowed safely should be determined by a dysphagia specialist at an individual level. |
| World Gastroenterology Organization global guidelines, 2014 ⁵⁸ | <ul style="list-style-type: none"> Oral feeding is best whenever possible. Modifying the food consistency to thicken fluid, and diet change with softer foods, can make an important difference. |
| National Institute for Health and Care Excellence CG Stroke rehabilitation ⁵⁹ | <ul style="list-style-type: none"> Offer swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gain. Swallowing therapy could include compensatory strategies, exercises and postural advice. |
| British Dietetic Association, 2006 ⁶⁰ | <ul style="list-style-type: none"> Patients who have chewing or swallowing difficulties need fluids and foods of a particular texture and consistency in order to eat without risk of choking or aspiration. |
| Scottish Intercollegiate Guidelines Network, 2010 ⁶¹ | <ul style="list-style-type: none"> Advice on diet modification and compensatory techniques should be given following full swallowing assessment. |

Table 2. Clinical practice guideline recommendations on compensatory management based of dysphagia

8. The benefits of commercial thickeners to achieve swallowing safety and swallowing efficiency in OD

Increasing the viscosity and/or limiting the volume of liquids is an important method of improving swallowing safety and swallowing efficiency in OD

patients (reducing penetration into the airway and the likelihood of aspiration). Several clinical and non-clinical studies reported that increasing the bolus viscosity from liquid to nectar and pudding by commercial thickeners significantly reduced the prevalence of laryngeal penetration and aspiration in patients with OD, indicating the beneficial effect of this technique. **Table 3.**

| Study | Design | N | Patient population | Interventions | Comparator(s) | Key outcome measure(s) |
|--|---------------------------------------|-----|--|------------------------------------|---|--|
| Steele CM <i>et al.</i> , 2019 ⁶² | Prospective, single blinded | 332 | Stroke or other brain injury aged ≥21 years; Other inpatients or outpatients with dysphagia risk, aged ≥50 years | Xanthan-based thickener (RTUC) | Thin liquid | Swallowing safety Efficiency of swallow as measured by rate of residue |
| Vilardell <i>et al.</i> , 2016 ⁵⁰ | Retrospective | 122 | Adults (≥18 years) with chronic post-stroke OD | Xanthan-based thickener (RTUC) | Thin liquid (mineral water) Starch-based thickener (RTU) | Prevalence of clinical and VFS signs of OD Incidence of aspiration Physiology of swallow response Residues quantity |
| Leonard <i>et al.</i> , 2014 ⁵³ | Prospective, randomised, double-blind | 118 | Adults (≥18 years) with dysphagia | Xanthan-gum based thickener (RTUC) | Thin (thin liquid barium) Starch-based thickener (RTU) | Incidence of aspiration PAS score |
| Rofes <i>et al.</i> , 2014 ⁶³ | Prospective, open label | 134 | Adults (≥18 years) with dysphagia (n=120) Healthy volunteers (n=14) | Xanthan-gum based thickener (RTUC) | Thin liquid | Prevalence of clinical and VFS signs of OD Physiology of swallow response Residues quantity |

Table 3. Clinical and non clinical studies on effect of viscosity in OD patients

Steele *et al.*⁶² carried out a prospective study to assess swallowing impairment in **322 individuals** in the US. The **safety and efficiency of swallowing was measured** using videofluoroscopy during **swallows of liquid barium stimuli in thin, mildly, moderately and extremely thick viscosities**. The results showed that:

- Swallowing safety improved as the thickness of the liquid increased from thin to mildly, moderately and then extremely thick.
- Impairments of swallowing efficiency (as measured by the presence of residue at the end of any swallow) were reduced with increasing thickness of the liquid swallowed.

This study supports the benefits of commercial thickener, based on xanthan gum, to improve the swallowing safety and swallowing efficiency of swallowing in patients with oropharyngeal dysphagia. This is in contrast to starch-based thickeners where residue increases with increasing viscosity.

Leonard *et al.*⁵³ conducted a prospective, randomised, double-blind study. They compared the **effects of viscosity on swallowing safety in patients with dysphagia (n=118)** when using either a xanthan gum-based thickening agent (Resource® ThickenUp Clear), thin liquid or a starch-based agent (Resource® ThickenUp). The results showed that:

- Thickened liquids were significantly effective in reducing the incidence of aspiration compared with a thin liquid, as measured by videofluoroscopy (VFS) instrumental evaluation (21.5% vs 50.0%; $p < 0.05$).
- The aspiration rate observed for the liquids thickened with xanthan gum was lower than that observed with a starch-based thickener, although the difference was not statistically significant (21.5% vs 28.5%; $p > 0.05$).

Vilardell *et al.*⁵⁰ compared the **effects of bolus viscosity of two commercial thickeners agents**, a xanthan gum-based thickener (Resource® ThickenUp Clear) and a modified-starch thickener (Resource®

ThickenUp) on swallow safety and efficacy in post-stroke adult patients with chronic oropharyngeal dysphagia (n=122). Patients were studied by clinical assessment (V-VST) and VFS methods using three viscosities (liquid 0–50 mPa.s, nectar 51–350 mPa.s and spoon thick >1750 mPa.s). Results from this study showed that:

- Increasing bolus viscosity with both thickeners improved safety of swallow in post-stroke patients with chronic oropharyngeal dysphagia, compared with thin liquids:

- With both thickeners, the prevalence of clinical signs of safe swallowing significantly increased with enhanced viscosity compared with thin liquid ($p<0.001$ vs liquid), as shown by significant reductions in voice changes ($p<0.001$ vs thin) and cough after deglutition ($p<0.01$ vs thin).

- The prevalence of penetrations and aspirations at nectar-like viscosity, as evaluated by VFS and measured by PAS, was significantly lower with Resource® ThickenUp Clear than with the modified-starch thickener (19.5% vs 44.0%, $p<0.01$).

- In contrast to liquids thickened with the modified-starch thickener, liquids thickened with the xanthan-gum thickener had a lower prevalence of pharyngeal residue across all of the viscosities tested (9.0% vs 25.0%, 33.8% and 51.8% for thin liquid, nectar- and spoon-thick, respectively), as measured by VFS evaluation.

Rofes *et al.*⁴³, conducted another prospective, open label study to **assess the effects of bolus viscosity using a commercial xanthan gum-based thickener (Resource® ThickenUp Clear) on the clinical signs of oropharyngeal dysphagia and on swallow function in dysphagic patients (n=120), compared with thin liquids.** Results from this study showed again that increasing bolus viscosity (from thin liquid to nectar-thick and spoon-thick) **improved the safety of swallow compared with thin liquid without increasing residue**, as demonstrated by:

- A significant reduction in the prevalence of cough ($p<0.05$ vs thin-liquid) and voice changes ($p<0.001$ vs thin liquid) as indicators of aspiration and penetration respectively. This was observed by a validated method of clinical assessment, the volume-viscosity swallow test (V-VST).
- Significant reductions in the prevalence of aspiration as measured by VFS instrumental evaluation: 12.7%

with thin-liquid, 7.7% with nectar-like ($p<0.01$) and 3.4% with spoon thick ($p<0.01$) viscosity.

- Significant reductions in prevalence of penetration and aspiration, as measured by PAS scores with use of VFS: 3.24 ± 0.18 with thin liquid, 2.20 ± 0.18 with nectar-like ($p<0.001$), 1.53 ± 0.13 with spoon-thick ($p<0.001$) viscosity.
- No significant increase in prevalence of oral or pharyngeal residue was observed at nectar-like viscosity, compared with thin-liquid.

In a large clinical trial, increasing bolus viscosity (from thin liquid to nectar-thick and spoon-thick) improved the safety of swallow compared with thin liquid, without increasing residue in dysphagia patients for xanthan-based thickeners.

9. Consistent Terminology to avoid variations of the Viscosity of Thickened Liquids

Prior to 2017, countries around the world had their own methods for naming and differentiating various levels of liquid thickness. The earliest recognised system for categorising foods and liquids used in dysphagia management was the **National Dysphagia Diet (NDD)** guidelines on thickened dietary supplements, developed by the American Dietetic Association and the National Dysphagia Diet Task Force in 2002.⁴⁴

The NDD guidelines categorised viscosity into thin, nectar-thick, honey-thick and spoon thick/pudding-like thickness levels (Table 4). Further the NDD provided guidance on the recommended thickness range for each of the thickness levels measured using a rheometer with liquids at a temperature of 20 °C measured at 50 s⁻¹. Over the years several studies demonstrated that the apparent viscosity of thickeners, when prepared according to manufacturer recommended methods, did not correspond to the expected thickness level according to the NDD.⁴⁵ Variability of this sort poses risks to patients. It is also important to note that the NDD scale was developed when **starch-based** thickeners were the norm. The subsequent development of shear-thinning xanthan gum-based thickeners further exacerbated the issue.

| Thickened fluid classification | Range of fluid viscosity |
|--|--------------------------|
| Nectar-like thickened liquids | 51–350 cP |
| Honey like thickened liquids | 351–1750 cP |
| Spoon thick/Pudding-like thickened liquids | >1750 cP |

Abbreviations: cP, centipoise. Measured at 20 °C, and shear rate of 50 s⁻¹.

Table 4. National Dysphagia Diet fluid viscosity scale

However, by 2013 it was apparent that different scales, labels and measuring methods had been developed for national use in Australia, Ireland, Japan, New Zealand, Sweden, the UK and Denmark. When reviewed, there were similarities and differences between the various scales.⁴⁶ **The variations posed risks to patient safety and limited the ability of clinicians or researchers to compare results of research and generalise their findings when thick liquids or texture modified foods were used therapeutically.**

In 2017, an international multidisciplinary group led the development of an international framework (IDDSI) to label, describe and measure liquids of different thickness and foods of different textures. In a survey of current practice from 2050 respondents from 33 countries, there was considerable variation in terminology used both within and between countries. However, most drink options recorded thin liquids plus three or more levels of progressively increasing thickness.⁴⁷

The IDDSI Framework provides a **common terminology to describe food textures and drink thickness**. IDDSI tests are intended to confirm the flow or textural characteristics of a particular product at the time of testing. Testing should be done on foods and drinks under the intended serving conditions (especially temperature) given that this is the condition the patient will consume the liquid. The clinician has the responsibility to make recommendations for foods or drinks for a particular patient based on their comprehensive clinical assessment. The framework was developed by evidence-based methods, including systematic review and stakeholder engagement from 33 countries.

The Framework consists of **8 levels** (0–7) where **drinks are measured from levels 0–4 and foods are measured from Levels 3–7** (See Figure 9). The Framework is identified by numbers, text labels,

colour codes, definitions and measurement methods. It is designed to be used for all people, of all cultures, and in all care settings.

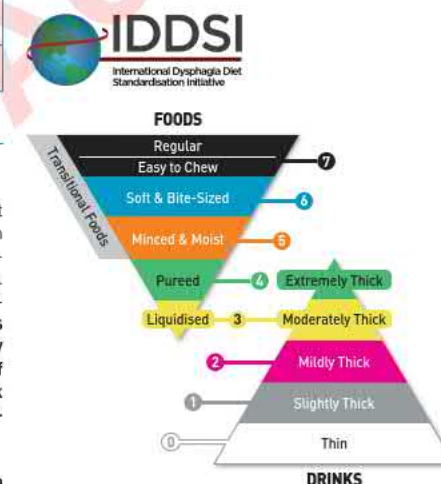


Figure 9. The IDDSI Framework: International Dysphagia Diet Standardisation Initiative 2019 @ <https://iddsi.org/>

The published literature prior to 2017 supporting the use of thickened liquids for the management of dysphagia uses nomenclature from **before IDDSI Standardised terminology** was in use. Table 5 provides an approximate conversion chart for reference. The national and international terminologies provide a method of describing thickened liquids. Some have accompanying methods of measuring liquid thickness. Although thickness is scaled from thinner to thicker, the scale itself does not imply safety. It is the clinician who determines the safety for any particular thickness level for the individual needs of the person.

For example, while individuals post stroke may benefit from a moderately thick or extremely thick liquid to reduce the likelihood of aspiration, a person recovering from head and neck cancer may be at risk on moderately or extremely thick liquids as they lack the tongue propulsion to drive the bolus far enough into the pharynx, potentially resulting in residue post swallow. Individuals recovering from surgery or chemo/radiotherapy may benefit more from mildly thick liquids.¹⁰

| IDDSI | NDD | Australia | UK | Japan |
|--------------------|---|-------------------------------|-------------------|-------------------------------------|
| 0 Thin | Thin (1-50 cP) | Regular | Thin | Less Mildly thick (< 50 mPa.s) |
| 1 Slightly Thick | No equivalent | No equivalent | Naturally thick | Mildly Thick (50-150 mPa.s) |
| 2 Mildly Thick | Nectar-like (51-350 cP) | Level 150 Mildly Thick | Thickened Stage 1 | Moderately Thick (150-300 mPa.s) |
| 3 Moderately Thick | Honey-like (351-1750 cP) | Level 400 Moderately Thick | Thickened Stage 2 | Extremely thick (300-500 mPa.s) |
| 4 Extremely Thick | Spoon-Thick (>1750 cP) *Pudding Thick | Level 900 Extremely Thick | Thickened Stage 3 | Over Extremely Thick (>500mPa.s) |

IDDSI – International Dysphagia Diet Standardisation Initiative; NDD – National Dysphagia Diet (USA)

*Spoon-Thick is also referred to as 'Pudding-Thick' in some dysphagia literature

10. Thickeners and thickened liquids for special medical purposes

Thickened liquids are rarely a liquid of choice, but one of necessity for safety. They are prescribed to improve swallowing safety and efficacy following a thorough evaluation by a qualified healthcare professional. Speaking very generally, the least viscous liquids are used to treat mild dysphagia whilst increasingly thicker liquids are used to manage more severe forms of dysphagia. However, prescription of fluid thickness is patient-specific and dependent on many variables that require careful evaluation by a qualified Healthcare Professional.

The prevalence of the use of thickened fluids has only been studied comprehensively for the aged care demographic. Of 25,470 residents in a skilled nursing facility, a mean of 8.3% and range of 0-28% of residents received thickened fluids for the treatment of dysphagia.⁴⁸ Most patients who required thickened liquids received nectar-thick fluids (30-60%), a smaller percentage received honey-thick fluids (18-33%), whilst only a small proportion received spoon-thick fluids (6-12%).⁴⁹ This finding is supported by recent studies demonstrating the therapeutic benefits of liquids tested in the range 150- 450 mPa.s, with no improvement on safety beyond 450 mPa.s for liquids of thickness 800, 1400 and 2000 mPa.s⁴⁹ for the cohort examined.

In a survey conducted with more than 2000 respondents over 33 countries, while considerable variation in terminology was noted, clinicians used thin liquids in addition to three or more levels of thickened drink for therapeutic purposes.⁴⁷ Of note, survey responses confirmed that paediatric and palliative care clients routinely used slightly thickened drinks for therapeutic purposes. These liquids have been measured at 80 mPa.s at 50 sec⁻¹ at room temperature.⁷⁰ Although the Bolivar-Prados survey noted benefit in liquids at 150 mPa.s, they did not test liquids thinner than that consistency.⁴⁹

Thickeners and thickened liquids "for the dietary management of dysphagia" are **regulated in the EU as "Food for Special Medical Purposes"** (FSMPs).

FSMPs are recognized as a specialized category of foods intended to be used by vulnerable patient populations, where specific legislation is critical to ensure FSMPs are appropriately labelled and marketed for their intended use. Without this specific categorization of food, it is difficult to ensure appropriate information is provided to the patient and health care professional.

FSMPs are defined in article 2(2)(g) of framework Regulation (EU) 609/2013. "FSMP means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a

limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone".⁷¹

The regulatory environment of FSMPs in the EU has been previously well described by Bushell & Ruthsatz.⁷² The authors show that the definition of FSMPs is broad enough to encompass a wide variety of FSMPs necessary to meet the specific nutritional needs of many diseases, including dysphagia. All elements of the FSMP definition must be taken into consideration, and not one element should be considered in isolation to include or exclude a product from this category. The levels set out in FSMP must be considered together with the clinical case that supports their use to determine their suitability for categorisation.

Taken together with the information above, **thickeners and thickened liquids for the dietary management of oropharyngeal dysphagia meet the definition of Food for Special Medical Purposes.**

- **Different from other food agents with thickening properties** such as flour, corn-starch and tapioca, thickeners based on starch or gums are specifically processed in order to achieve a stable and appropriate texture free of lumps that are safe to be swallowed by patients suffering from dysphagia.
- **The use of thickeners under medical supervision is of paramount importance for the safety of the patient.** Thickeners are the main therapeutic pillar for dysphagia management regardless of healthcare or community setting, and regardless of age. Appropriate treatment and management by a qualified Healthcare Professional is essential for the prescription of the appropriate thickener and thickness level to best meet the person's needs from their thickened liquid for hydration and medication transfer purposes.
- **The intended use of thickeners is to enable safe feeding of patients with dysphagia, who cannot eat ordinary food or drinks without the risk of aspiration.** The prescription of thickened liquids helps to prevent common complications such as dehydration, pneumonia, reduced quality of life and economic burden.
- **The measure of whether it is possible to achieve the required nutritional intake by modification of the normal diet must be considered in the context**

of the patient and the challenges of their disease or medical condition. The Commission Notice on the Classification of Food for Special Medical Purposes [48] explains that FSMPs **may offer nutritional and clinical advantages to patients over and above a modification of the normal diet alone.** This must be taken into account, even if to some extent a modification of the normal diet may address the nutritional requirements of dysphagia patients.

The field of dysphagia is relatively young with concerted research occurring over the last 30 years. The development of thickener types to manage dysphagia is progressing rapidly. The learnings about different thickening agents underscore the importance of understanding their conditions of use for patient safety. **To date thickener companies have provided dose rates on packaging to assist clinicians and patients to achieve particular thickness levels.** Recent research consistently demonstrates that doses for the different thickness levels need to be tailored to the product being thickened. For example, to achieve the same thickness level, the amount of thickener added to water is different to the amount of thickener added to milk.⁷³ **Manufacturer labelling should clearly state the liquid used to develop the thickener dose to achieve a range of thickness levels.** However, clinicians need to work with their patients to **determine individual dosages to suit each patient's individual needs, assessing the thickness level prior to serving to ensure safety.**⁷⁴ Education is required to ensure that clinicians understand that a single dose recipe per thickness level, regardless of liquid type, is an unrealistic and unsafe expectation. In much the same way that medical professionals will adjust medication dose to manage symptoms at an individual level, the same is true of thickener prescription for the management of dysphagia.

11. Ingredients of thickening agents used in clinical practice for the dietary management of individuals who suffer oropharyngeal dysphagia

The development of thickening agents specifically for the treatment of dysphagia has advanced over the years. Although food agents such as flour, cornstarch and tapioca have for centuries been used to thicken culinary items such as sauces and gravies, these items are unsuitable for use as thickening agents for people with dysphagia. Flour and corn starch clump. They are

difficult to prepare, requiring heat to help them swell and absorb water. They are unstable, losing their thickness with prolonged stirring, heating or when mixed with acids (e.g. lemon juice). Early thickening agents used for dysphagia in the 1990's used modified starch that overcame the heating process to allow powdered starch to be added to cold beverages for thickening purposes. However, research published circa 2005 demonstrated problems with stability of starch-based thickening agents. Garcia *et al.*⁷⁵ found that 80% of samples thickened with starch-based thickeners became thicker 10 minutes following the standard wait time and one third thicker again 30 minutes post the standard wait time. In contrast, the gum-based thickeners maintained their thickness level at the end of standard waiting time, and 10- and 30-minutes post standard waiting time. Similar results were reported by Matta *et al.*⁷⁶ confirming good stability of gum-based thickeners. Older generation starch-based thickeners were cloudy in appearance, whereas new generation gum-based thickeners have a 'clear' appearance.

11.1. Starch-based thickening agents

Starch-based thickening agents are composed of modified starch, carbohydrate granules that have the capacity to absorb water and swell, causing an increase in liquid viscosity.⁷⁶

Starch-based thickeners are associated with limitations such as a starchy taste and grainy texture.⁷⁶ Accurate viscosity is difficult to achieve when using starch-based thickeners due to starch settling in the solution resulting in a loss of viscosity⁷⁷, clumping and production of lumps from poor incorporation of the starch powder with the liquid or the starch solution continuing to absorb liquid and thickening over time.⁷⁸ Starch granules can be also hydrolysed by amylase, an enzyme present in saliva which breaks down starch. If the bolus stays in the oral phase for a long period of time (e.g. 10 sec +), the starch-based bolus may be broken down before it is swallowed, increasing risk of airway invasion.⁷⁹ Anecdotally, clinicians have also reported that a spoon coated in saliva that is repeatedly dipped into a container of starch thickened liquids, results in a thinning of the liquid over time.

Liquids thickened with starch require a greater number of tongue actions to successfully swallow pudding thick liquids. More recently an *in vitro* swallowing model showed that there is more post-swallow residue left in the pharynx when thicker boluses are swallowed compared with thinner boluses.⁸⁰

11.2. Gum-based thickening agents

The new generation of thickening agents are composed of hydrocolloids, such as xanthan gum. Xanthan gum causes meshes of entanglements that water molecules become lodged in, creating stable networks that maintain viscosity levels over time. Xanthan gum thickeners offer improved palatability and are not degraded by amylase. Xanthan gum is stable in both hot and cold temperatures offering an ability to thicken hot and cold beverages.⁷⁹ This feature is important to patient compliance taking thickened liquids and therefore the ability to meet hydration targets. Due to the ability to maintain viscosity over time, improved palatability over starch-based powders and lack of sensitivity to amylase, xanthan gum-based thickeners are currently the established choice in clinical practice.

The performance characteristics of starch and gum based thickened agents are compared in Figure 10, with reference to ideal bolus attributes.

As noted previously, lower oral and pharyngeal residues are noted for xanthan gum thickened liquids as compared to starch thickened liquids.⁸⁰ The benefits associated with xanthan gum have been proposed to be related to its elastic nature and higher extensional viscosity when compared with starch thickened liquids. Mackley *et al.*⁸¹ assessed the shear and extensional rheology of starch thickened liquids, combination (starch + gum) thickened liquid and xanthan gum thickened liquid. Starch thickened liquids were found to have fast filament decay, breaking quickly and easily. The combination thickened liquid showed cohesion with thinning of the filament before breaking while the xanthan gum thickened liquid showed extended filament holding abilities. Mackley noted that the results for xanthan gum were showed a shorter filament break up time compared with Newtonian liquids at a similar low shear viscosity. Of interest, all three sets of thickened liquids had very similar shear rheology profiles compared with the marked differences noted for the extensional rheology profiles.⁸¹ Factors associated with cohesion, adhesion and surface tension clearly warrant further investigation.

Some studies have suggested that xanthan gum thickeners may affect the bioavailability of water in the body and contribute to dehydration due to the reduced extraction of water from xanthan gum-thickened liquids.⁷⁵ However, well-designed studies have demonstrated that water was rapidly absorbed and equilibrated within 60 minutes with water

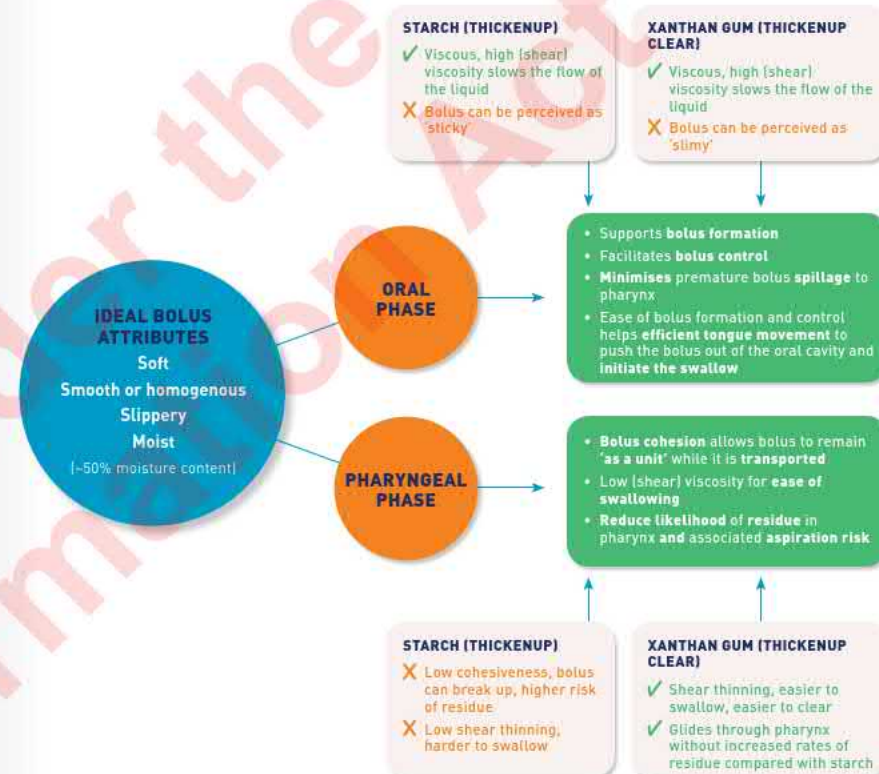


Figure 10. Performance characteristics of starch and gum based thickening agents referenced against ideal bolus attributes

absorption exceeding 95% of the administered dose of Extremely Thick liquids, suggesting that the bioavailability of water is not compromised when using thickening agents.⁸²

If there is sufficient availability of water from thickened liquids, then other factors must influence dehydration commonly associated with dysphagia. Hospitalised individuals, regardless of dysphagia status, have been found to have insufficient access to containers of liquids, difficulty opening drink containers, and difficulty accessing staff to assist them with drinking.⁸³ Increasing levels of thirst have been statistically associated with increased levels of disability in a study of patients on oncology, orthopaedic and general medical wards. Steps

can be put in place to improve access to thickened liquids, however a more challenging variable needs to be addressed. Specifically, thickened liquids do not have the same thirst-quenching characteristics that regular unthickened liquids possess. When the mouth is wet, as occurs with an influx of saliva and wetness provided by liquids, oral signals are conveyed to the brain to signal that thirst has been quenched and drinking behaviour can cease. However, thirst will persist if the oral phase is bypassed, even if the person is physiologically hydrated by direct infusion of water to the stomach.⁸⁴ Anecdotally, individuals with dysphagia complain of thirst and that thickened liquids leave a coating feeling inside the mouth. This feature is not specific to individuals with dysphagia, with a study showing that healthy individuals reported

that thirst sensation progressively worsened with increasing viscosity.⁸⁵

In addition to challenges associated with thirst quenching ability, thick liquids also result in poor flavour release. A number of studies have demonstrated that once polymers reach the critical point of random coil overlap [c^*] and form entangled networks, flavour perception decreases with increasing viscosity.⁸⁶ Flavour suppression and 'off flavours' of thickened liquids have been reported by Matta *et al.* Starch based thickeners were found to impart a starch flavour and a grainy texture for nectar- and honey-thick consistencies. Gum based thickeners did not produce grainy textures but do produce a higher 'slickness' than starch-based thickeners. Flavour suppression was demonstrated for all thickening agents. A combination of poor flavour plus poor thirst-quenching ability may help to explain why patients consume less thickened liquids than unthickened liquids. The ability to target the thickness level that is just sufficient to manage the swallowing problem is a clinical skill that is necessary for swallowing safety and patient compliance. Although thickener recipes can be provided, ultimately it is the clinician's responsibility to determine what is safest for each patient.

11.3. Gellan Gum thickening agents

Gellan gum is a viscous soluble fibre that has stability over a range of pH and temperatures. It is a widely used gelling agent used in pharmaceutical formulations. Gellan gum has been developed as a thick oral gel vehicle to administer the drug carbamazepine as an alternative to solid oral dosage forms (e.g. tablets/pills).⁸⁷ Gellan gum provides a stable and consistent viscosity in solutions that are mixed with saliva containing ions, mucin and alpha amylase. These properties of saliva have been shown to thin out liquids that have been thickened with modified starch and to a lesser extent starch-gel combination thickener.⁸⁸

11.4. Acacia Gum thickening agents

Acacia gum, also known as gum Arabic, is one of the oldest natural gums and can be described as a gummy exudate from Acacia Senegal and Acacia Seyal trees. It is a complex polysaccharide with soluble fibres and in its natural state is of low viscosity. Acacia gum is highly soluble in cold temperature and water up to concentrations of 50-55% and has been widely used

as a stabiliser, thickener, and flavouring agent.⁸⁹ However, acacia gum is poorly soluble in liquids other than water. There is an exponential increase in viscosity with increasing concentration of Acacia Gum. Of interest, acacia gum displays low viscosity even at high concentrations and does not gel. Unlike the other thickening agents, the flow of acacia gum solutions at certain concentrations results in Newtonian flow behaviour at concentrations below 20% weight, meaning that there is a linear relationship between shear rate and shear stress. This is particularly the case when the shear rate is 100 s^{-1} or above. In practical terms this is important for swallowing, particularly for people with poor tongue propulsion. There are benefits when flow is able to occur in proportion to the stress applied to the liquid as opposed to needing to use energy to generate a force to overcome the resistance to make the liquid flow. Imagine the ease of pushing a box along a layer of rollers, compared with the effort associated with pushing a box along a static bench. Due to its inherent nature, acacia gum is hypothesised to provide the liquid equivalent of rollers allowing the bolus to glide easily with the movement of the tongue. This effect is evident at certain concentrations with shear thinning behaviour (i.e. the solution becomes thinner as the shear rate increases) occurring at low (1-4%) and high concentrations of acacia gum (20% and higher). The surface properties of acacia gum are quite unique. It is this feature that provides its ability to form a layer over the surface on which it is travelling to allow the liquid to glide easily and is demonstrated in its Newtonian nature. Furthermore, it is able to do this while remaining thick, but elastic gel-like and highly cohesive.

11.5. Carageenan thickening agents

Carageenan is a naturally occurring polysaccharide extracted from red seaweed. It is widely used in the food industry because of its physical properties such as gelling, thickening and dehydrating and is safe for human consumption. This product works by swelling and producing layers of gel. The viscosity of carageenan increases exponentially with concentration.⁹⁰ Carageenan solutions are highly affected by temperature and show a significant increase in yield stress at low temperature when compared with xanthan gum and starch-based solutions (Marcotte, 2001). Many products, including soymilk, chocolate milk in particular and other flavoured milk, dairy products and nutritional supplements rely on carrageenan for their uniform consistencies and stability for packaging and storage.⁹⁰

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From: Withheld under section 9(2)(a)
Sent: Friday, 12 March 2021 4:59 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Food thickener feedback

Kia ora,

It is timely that PHARMAC is seeking consultation regarding the current inequitable access to funded food thickeners in the community. Having a family member with the lived experience has highlighted the current disparity between the community schedule and hospital medicines. We were informed the difference in funding provision was due to food thickeners being deemed beneficial during the acute phase of dysphagia. However, if Mum is admitted to hospital she is routinely prescribed "Precise Thick-n-Instant" despite being in the chronic phase of dysphagia. The inconsistency is further highlighted with inequitable access to food thickener in the community due to it only being funded for Motor Neurone Disease (MND), even though the cause of dysphagia has no bearing on the effect of therapeutic treatment. Quite simply, Mum is discriminated against due to post stroke seizures resulting in dysphagia. Interestingly, access to funded food thickener in the community for those with MND also nullifies the argument that therapeutic treatment is only beneficial in the acute phase of dysphagia. If the benefit of food thickeners was limited to only a select group/s due to conclusive research it could be considered a reasonable rationale, however this is not the case and the inconsistency is discriminatory as noted in the July 2002 Neurology Sub-committee minutes.

PHARMAC has been receiving requests to widen access to food thickeners for twenty years. It is disappointing the issue is still yet to be resolved despite expert recommendations and The Pharmacology and Therapeutics Advisory Committee (PTAC) Special Foods Subcommittee accepting the therapeutic benefits of food thickeners and the current inequitable access. The Special Foods Subcommittee PTAC July 2001 meeting "noted that there is almost universal support for wider access to subsidies. The subcommittee agreed that the current situation, whereby only patients with motor neurone disease (MND) can access subsidies was unfair and inequitable. It did not consider the clinical need or benefit for/of food thickness in patients with MND was any higher than for any other group of patients identified in the submissions". In October 2006 "The sub committee recommended that the Special Authority criteria for food thickness be amended to include all dysphagic patients on recommendation from a registered Speech and Language Therapist following consultation". Again in 2008 the Special Food subcommittee noted it was discussed at the 2007 meeting and was "recommended to widen access to include dysphagia as diagnosed by a defined swallowing assessment". Furthermore, it was acknowledged in 2013 under decision criteria four that "food thickeners are beneficial to patients suffering from dysphagia who otherwise risk aspiration".

I appreciate PHARMAC operates within financial constraints. Food thickener is a longstanding treatment option for dysphagia, not some new experimental drug with an astronomical price tag, so comparatively it is a low cost option. Widening the criteria would still only be a minimal proportion of the overall budget due to the very small percentage of people who are assessed as needing food thickener. Due to the undesirable nature of food thickeners, it will also not be consumed unnecessarily, therefore eliminating any potential concern regarding budgetary misuse. Cessation of food thickener due to the individual financial barriers for many people result in hospitalisation where it would then be not only funded but incur further medical cost. It is pertinent to note that The International Dysphagia Diet (IDDSI) which outlines the classification for thickening foods and fluids was adopted in 2018, so is used throughout the New Zealand health system and supported by the Health and Disability Commission.

In our situation food thickener is a necessity of life for Mum and reduces the risk of recurrent aspiration pneumonia causing death. It has enabled oral intake to be continued whilst maintaining adequate nutrition and hydration. The suggestion to use smoothies to gain suitable thickness for drinks is not plausible due to dairy intolerance, it is also unreasonable and unnecessarily restricting the diet. Food is a very pleasurable experience so being forced to

transition to peg feeding for economic reasons would result in a significant reduction in the quality of life and a greater financial cost to PHARMAC. Food thickeners have holistic benefits for Mum, yet due to being unfunded it is a financial burden and emotionally distressing being marginalised with her life being deemed as having less value. It is inconsistent, unethical and completely illogical that tube feeding is funded, yet food thickener to maintain oral intake is prevented in the community.

Funding food thickener is most certainly a simple, cost effective solution compared to tube feeding and hospital admissions. I urge PHARMAC to amend the food thickener funding criteria to enable equitable access for all New Zealanders. If it was your family member, how would you feel reading the recommendation "By not widening access the extra portion of the pharmaceutical budget could be channelled towards other pharmaceuticals identified by PTAC and its subcommittees as being higher priority and a better investment"? Whilst it is a very small proportion of the population each one has a right to life. Their lives matter!

Ngaa mihi
Withheld under
Section 69(1)(a)

From: Withheld under section 9(2)(a)
Sent: Sunday, 14 March 2021 11:23 pm
To: Consult <Consult@Pharmac.govt.nz>
Subject: Funding of Thickeners for MS, PPMS & PMS

Dear Sirs

I am aware I am submitting this application for funding slightly out of time but trust you will take the time to read through it.

I am a Withheld under section and have Progressive Multiple Sclerosis

MY BACKGROUND

I have always maintained my fitness, even climbing Kilimanjaro at 16 years old! Two years later I began tripping. Despite MRI's and nerve conduction tests and a lot of "doctor shopping" as my "condition" worsened, I was not diagnosed for another 2 years. Finally it took a top NZ Neurologist in Withheld to tell me I had Multiple Sclerosis. I attended Withheld under and advised as it was now PPMS and, according to my neurologist, the side effects of any treatment would negate any "improvement" which would be minimal to none. I've kept up my exercise and take supplements to keep the deterioration down. 3 years ago, despite being on a Keto diet to control demyelination, I was diagnosed with Progressive Multiple Sclerosis. My MRI results have been good and no further demyelination the last 2 years, just the physical deterioration. Despite this, last year my voice started going. I was advised it was part of PMS as my throat muscles became affected. Then I started choking on my food and drink. Being advised it was Dysphagia. Controlling my food was easy as I eat softer foods. I was advised to take thickener with my drinks but I would have to pay privately as it was only funded by Pharma if you had Motor Neurone Disease. I am puzzled why one autoimmune with speech and swallow disorder supersedes others with regard to funding. Even some heart defects have to have thickeners. The following link to MS Swallow and Speech sets out the difficulties, almost mimicking Motor Neurone
<https://www.msnz.org.nz/speech-swallowing/>

I would request a rethink of the funding for Thickeners, so that MS and any other heart/autoimmune disorders would be included.

I pay approximately \$15 + postage each online or if bought in a mobility shop between \$30 \$40 each.

I use 1 500g tin a week, some people would use more

Some people may not be able to afford this, therefore put themselves at a risk of pneumonia.

Dysphagia doesn't just affect Motor Neurone patients.

Thank you for your time in reading my submission and look forward to hearing from you

Yours sincerely

Withheld under

Withheld

Withheld under

From: Loraine Hamm (NDHB) <[redacted]>

Sent: Monday, 15 March 2021 7:49 am

To: Consult <Consult@Pharmac.govt.nz>

Subject: Pharmac funding of thickeners feedback

Attached please find my feedback on thickeners.

Regards

Loraine

Loraine Hamm

Speech Language Therapist
Paediatric Feeding and Communication
Professional Advisor Speech Language Therapy
Northland District Health Board

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(a)



The opportunity to communicate is a basic human right

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1. In what clinical situation would a person be started on a food thickener?
 - a. Is there a way to clearly define those people with dysphagia who are most likely to need, or benefit from, use of a food thickener? Is this based on severity of dysphagia?

Paediatric clients:

The most likely clinical situation for starting a food thickener would be a child with recurrent respiratory illnesses who demonstrated aspiration or penetration during Videofluoroscopic Study of Swallowing (VFSS) and who demonstrates reduction in these markers with trial of thickened liquids during the study.

"A well-executed videofluoroscopy study not only provides evidence for aspiration but will also explore relative risks for different consistencies of feed and optimal posture during feeding. Advice regarding volumes, cups, spoons, bottles and teats, posture, thickeners, and consistency can significantly improve the aspiration risk and consequent lung health." (Wallis C, 2012)

As regards severity "Although aspiration is considered more pathologic than penetration, penetration is also associated with risk for pneumonia" (Gurberg J, 2015)

The emerging evidence suggests that: "Thickening or other feeding intervention should be considered for all symptomatic children with laryngeal penetration on VFSS." (Duncan D R, 2019)

Another clinical situation that may present would be where a child is not able to manage thin liquid orally due to inco-ordination often in the presence of neuromotor impairment e.g. cerebral palsy. Thin liquid may spill out of the mouth due to lack of oral control. Thickening may enable the child to maintain oral intake as the slower flow of the liquid may support better oral control and safe swallowing

- 2 How many people are currently using food thickeners (either funded through the Pharmaceutical Schedule, or funded by other means)?
 - a How many people might have dysphagia and benefit from the use of food thickeners?

In our small-medium DHB we have completed 17 VFSS in 2020 and thickener was recommended for 8 of these patients, approximately 50%. No thickener for paediatric patients is currently funded through Pharmaceutical Schedule. These patients may be eligible for a disability allowance to fund expenses like thickener.

- b. How many people currently living in care facilities (e.g. rest homes) have dysphagia that might benefit from the use of food thickeners?

Not applicable for paediatric patients.

3. Who usually makes the decision to start someone on food thickeners?
 - a. How is this decision to start someone, for long-term use, on food thickeners made?

Paediatric Speech Language Therapists will recommend thickening based on the outcome of the Videofluoroscopic Study of Swallowing in liaison with the MDT and with consideration of the full clinical presentation.

4. How often is the use of food thickeners reviewed?
 - a. How long is someone usually on food thickener(s) for?

This is highly variable from a few months to several years.

"Oropharyngeal dysphagia can also occur in infants without any detectable risk factors who present with unexplained respiratory problems. This may represent some form of delay in the maturity of their swallowing integrity. The prognosis for resolution in these children is good, although it can take years. (Wallis C, 2012)

"Laryngeal penetration is not transient in children under 2 years of age and may be indicative of aspiration risk." (Duncan D R, 2019)

In children with neuromotor impairment there is frequently not resolution, but feeding therapy, including the use of thickener, may optimise oral intake with reduced mortality and morbidity. In these patients thickening may be needed throughout their lifetime at significant personal cost.

- b. What evidence/guidance/guidelines are used to support long term use of food thickeners?

We are consistently being led by emerging evidence from the literature, by clinical experience and by patient experience.

- c.

Thickening is consistently reviewed for tolerance and the impact on intake, gastro intestinal effects, allergic responses and symptom reduction. This is done in liaison with Dietitians and the wider MDT team. Once it has been established that thickening is well tolerated and achieves the therapeutic goals there will usually be at least annual review.

5. What are the goals of therapy when using food thickeners e.g. prevention of aspiration, nutrition, hydration, quality of life?
 - a. How much do food thickeners help achieve these goals?

"The goals of feeding therapy are to provide nutrition safely and efficiently, prevent lung injury, preserve respiratory function, and permit appropriate growth." (Das S, 2020)

"The lung is the primary end organ of damage secondary to aspiration. The injury may occur anywhere along the respiratory tract but most consistently results in chronic bronchiolar inflammation and injury, in a dependent distribution. Bronchiectasis is a common result and may develop even in infants." (Piccione J C, 2012)

- i. What evidence is available to support this?

In their May 2019 "Clinical Aspects of Thickeners for Paediatric Gastroesophageal Reflux and Oropharyngeal Dysphagia" Duncan R et al provides a summary of reported effect of thickening feeds in studies completed between 2001 and 2018. (Please see article: Table 1) (Duncan D R, 2019)

A study by the same authors "Feeding interventions are associated with improved outcomes in children with laryngeal penetration" adds to this in that their subjects had "decreased total and pulmonary hospitalizations with feeding intervention and decreased pulmonary nights with thickening. (Duncan D R, 2019)

- b. Are there any clinical risks associated with thickening food and/or liquids in people diagnosed with dysphagia?

For a recent summary of risk factors see discussion on risk in abovementioned article. (Duncan D R, 2019)

In their risk:benefit analysis the authors conclude that: " From an oropharyngeal dysphagia perspective, the alternative to thickening would involve continued aspiration with increased pulmonary morbidity, hospitalizations, and ER visits in addition to increased placement of enteral tubes; again the thickening safety profile relative to the alternatives is favorable."

Risks are also discussed in the 2020 literature review-UpToDate- (Das S, 2020) and the author concludes that "Use of thickeners is generally low risk, but a few safety considerations have been raised:"

6. Are there any people/patient groups where the use of a food thickener may prevent the need for a feeding tube?
 - a. If so, which people/patient groups?

Paediatric patients with recurrent respiratory illnesses and hospitalisation who may not be able to manage oral thin liquids but who may be able to manage thickened liquids safely.

Paediatric patients who may not be able to manage the full volume of liquids required as thin fluids but who may be able to increase their intake with thickened liquids e.g. patients with cerebral palsy.

It also needs to be considered that “Use of thickeners for oral feeding has been shown to reduce respiratory symptoms and hospitalizations compared with unmodified feeds and even compared with infants being fed via gastrostomy.” (Das S, 2020)

b. For how long would the use of food thickeners delay the need for a feeding tube?

If therapeutic goals are met by thickening for children with respiratory symptoms feeding tubes can be avoided completely.

“Thickening of feeds can even reduce the need for gastrostomy tube placement in children with aspiration” (Duncan D R, 2019)

In some children with neuromotor impairment there may be need for tube feeding if their growth needs outweigh their ability to take in sufficient nutrition.

7 How is someone's quality of life improved by a food thickener?

Recurrent respiratory illnesses and hospitalisation in a baby or child not only affects the quality of life of the child, but that of the whole family. Recurrent illness and hospitalisation impacts on the physical wellbeing of the child and in young babies and children on their development. Young children may miss out on educational opportunities.

There is an emotional impact on the parents and extended family in terms of dealing with recurrent illness in their child; there is significant financial impact on the family. Many of our families need to travel up to 2 hours to their regional hospital and transfer to the base hospital will incur further traveling expenses. There is the social burden of care for other children when the parents need to spend time in hospital with an unwell child and not being able to maintain their work/business life. Chronic illness can impact on the mental health of parents and caregivers.

Prevention of tube dependency can also enhance quality of life in that there is reduced need for medical interventions e.g. frequent home/hospital visits to replace and/or manage tubes; normalisation of home and social life.

Maintenance of eating and drinking in the child with neuromotor impairment (disability) will enhance their quality of life through reduced medicalisation and enhanced ability to participate in home, community and educational activities.

a. How is any improvement in quality of life demonstrated or measured?

Improvement is primarily measured in terms of reduced respiratory symptoms and reduced hospital admission which will impact on all aspects of quality of life.

b. What evidence is available to support this?

The emerging evidence suggests that: “Thickening of liquids and, to a lesser extent, reduction in flow rate reduce symptoms and respiratory hospitalizations. This has been demonstrated both in infants and young children who have aspiration on videofluoroscopic swallow study(VFSS) and those with penetration alone” (Duncan D R, 2019)

- 8 Are there any other available products (funded or unfunded) that achieve the same goals as food thickeners aim to achieve? No
- 9 We are aware of a range of different types of food thickeners (e.g. natural, liquid thickeners, powder thickeners). Do these all achieve the same goals?
Yes some thickeners are not recommended for babies and children.
 - a. Are there different benefits associated with different types of food thickeners?
No
- 10 Any other comments?

Babies/children of Maori and Pacific Island descent are disproportionately affected by respiratory illnesses and the progression of illness to chronic disease in New Zealand.

Uninterrupted maintenance of thickening of feeds, where it is indicated, is essential to ensure that babies/children benefit from the intervention.

The cost of thickeners impacts on the ability of low income families to maintain uninterrupted maintenance of thickening for their babies/children and can therefore directly impact on their health.

Thickeners are not readily available for purchase in many communities, especially smaller towns and rural areas in New Zealand and online purchases are frequently not an option for families with low resources as regards finances, internet access etc. Families with limited resources are therefore left at a disadvantage having to negotiate with local pharmacies to secure a continuous supply of thickener

Easier access to thickener will also support the MOH initiative to reduce Ambulatory sensitive hospitalisations (ASH) i.e. admissions that are reducible through prophylactic or therapeutic interventions

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