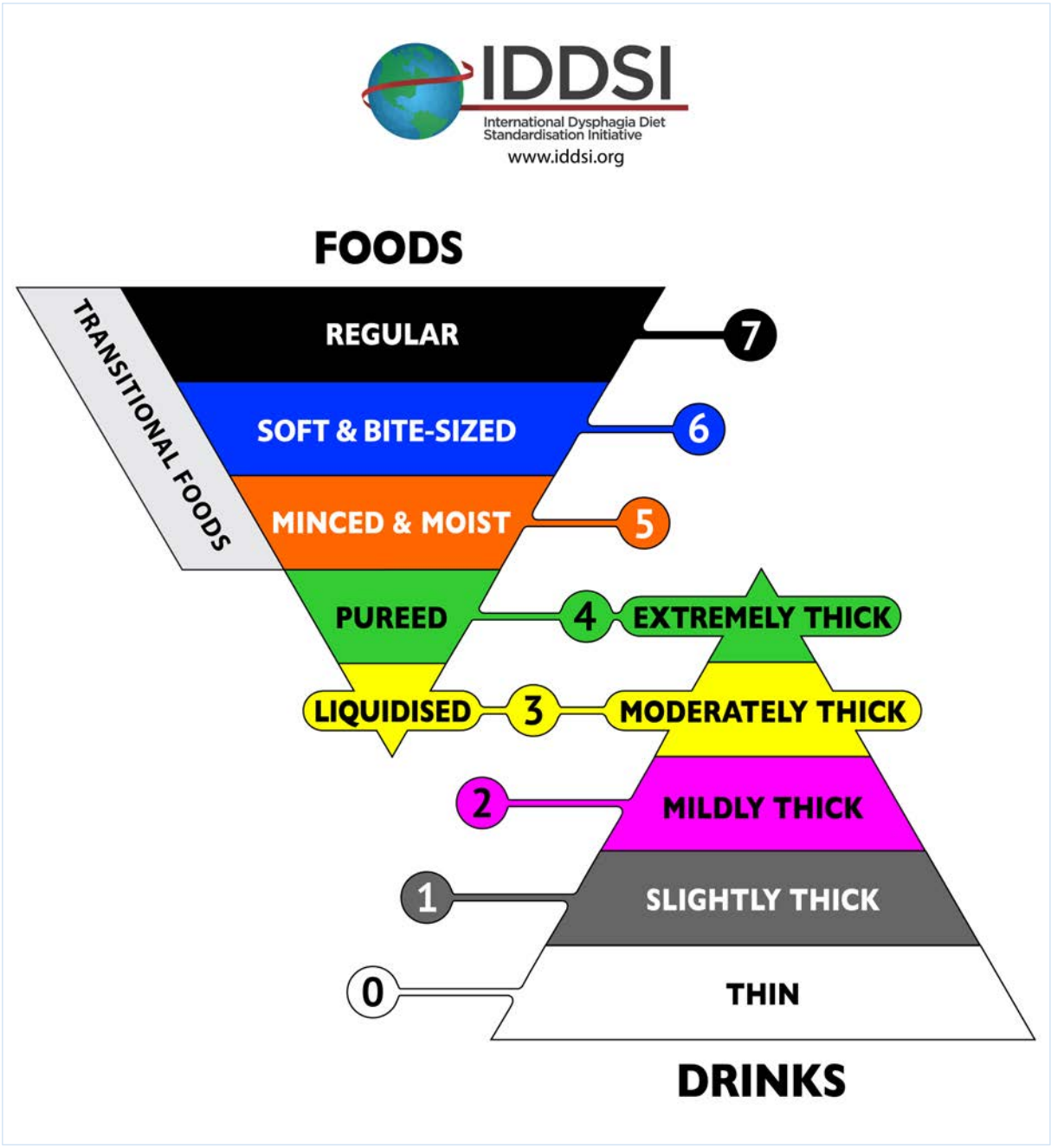

IDDSI Framework
Evidence Statement

October 10, 2016

INTRODUCTION

The International Dysphagia Diet Standardisation Initiative (IDDSI) was founded in 2013 with the goal of developing new global standardised terminology and definitions to describe texture modified foods and thickened liquids used for individuals with dysphagia of all ages, in all care settings, and all cultures.

Three years of ongoing work by the International Dysphagia Diet Standardisation Committee has culminated in a final dysphagia diet framework consisting of a continuum of 8 levels (0-7). Levels are identified by numbers, text labels and colour codes.

This document provides details regarding Levels of Evidence that support the IDDSI Framework.

This document is to be read in conjunction with the Complete IDDSI Framework, IDDSI Testing Methods and IDDSI Frequently Asked Questions (FAQs) documents(http://iddsi.org/resources/framework/).

The IDDSI Committee would like to acknowledge the interest and participation of the global community including patients, caregivers, health professionals, industry, professional associations and researchers. We would also like to thank our sponsors for their generous support.

The IDDSI Committee:

Co-Chairs: Peter Lam (CAN) & Julie Cichero (AUS);

Committee Members: Jianshe Chen (CHN), Roberto Dantas (BRA), Janice Duivestein (CAN), Ben Hanson (UK), Jun Kayashita (JPN), Caroline Lecko (UK), Mershen Pillay (ZAF), Luis Riquelme (USA), Soenke Stanschus (GER), Catriona Steele (CAN).

Past Committee Members: Joe Murray (USA)

The International Dysphagia Diet Standardisation Initiative Inc. (IDDSI) is an independent, not-for-profit entity. IDDSI is grateful to a large number of agencies, organizations and industry partners for financial and other support. Sponsors have not been involved with the design or development of the IDDSI framework.

Development of the IDDSI framework (2012-2015)
IDDSI would like to thank and acknowledge the following sponsors for their generous support in the development of the IDDSI framework:

- Nestlé Nutrition Institute (2012-2015)
- Nutricia Advanced Medical Nutrition (2013-2014)
- Hormel Thick & Easy (2014-2015)
- Campbell's Food Service (2013-2015)
- apetito (2013-2015)
- Trisco (2013-2015)
- Food Care Co. Ltd. Japan (2015)
- Flavour Creations (2013-2015)
- Simply Thick (2015)
- Lyons (2015)

Implementation of the IDDSI framework is in progress. IDDSI is extremely grateful to all sponsors supporting implementation http://iddsi.org/about-us/sponsors/

Evidence to support the IDDSI Framework

A systematic review of the literature was conducted to examine the impact of drink thickness and food texture on swallowing behaviour across the age spectrum. The systematic review was peer-reviewed and published Open Access in the Dysphagia Journal (Steele et al., 2015 Dysphagia, 30(1): 2-26; doi: 10.1007/s00455-014-9578-x).

Liquids

With regards to liquids, the results of the systematic review determined:

- Thicker liquids reduce the risk of penetration–aspiration, but also increase the risk of post-swallow residue in the pharynx
- The literature was insufficient to support the delineation of specific viscosity boundaries or other quantifiable material properties related to these clinical outcomes

Of the 36 studies that met the eligibility criteria for the systematic review, 26 related to function in healthy populations whilst only 10 were related to individuals with dysphagia. Of these 10 studies, one related to infants and the remainder investigated swallowing function in adults with neurological or neurogenic conditions, or dysphagia associated with treatment for oropharyngeal or nasopharyngeal cancer.

The results of IDDSI's international stakeholder surveys demonstrated common use of thin drinks plus three levels of increasing drink thickness for the management of swallowing problems across the age spectrum. The systematic review also found research investigating the impact of thickened drinks according to this general framework (i.e., thin drinks plus three levels of increasing thickness) and described using labels previously found in previous national terminologies such as Nectar/Syrup/Level 150/Mildly thick; Honey/Custard/Level 400/Moderately thick and Pudding/Spoon thick/ Level 900/Extremely thick (Steele et al., 2015, Dysphagia, 30(1): 2-26). In addition, paediatric stakeholders reported common use of a drink thicker than water but thinner than the commencement point of thickened liquids commonly used for adults. This level has been incorporated into the IDDSI Framework as Level 1 – Slightly Thick. Level 1 – Slightly thick drinks has also been verified as distinct from other thickness levels in the literature, however, as with all other thickened liquids, this level lacks data to determine the exact thickness required for therapeutic benefit.

Given the paucity of research regarding therapeutic thickness levels for thickened drinks, the IDDSI framework is based on an understanding that increasing thickness has a demonstrated therapeutic benefit for reducing the risk of penetration/aspiration. The number of levels of drink thickness included in the framework and recommended for best practice is based on clinical experience, stakeholder consensus and expert opinion.

The systematic review points to an urgent need to conduct quality research to determine thickness levels that provide therapeutic benefit by reducing risk for penetration/aspiration and/or improving swallowing function.

Foods

With regards to foods, the results of the systematic review determined:

- The best available evidence regarding the selection of an optimal food consistency for a person with dysphagia comes from the careful exploration of tolerance for different foods in a comprehensive clinical swallowing assessment;
- Thicker and harder items require greater effort in oral processing and swallowing

- Note, terms related to choking, airway obstruction or asphyxiation were *not* included in the search strategy for this review

Of the 36 studies that met the eligibility criteria for the systematic review, 18 studies related specifically to food with one article covering both healthy adults and children. 12 studies related to healthy adults and two related to healthy children whilst five related to adults with dysphagia. Of these five studies, two related to neurological conditions, two specifically to stroke, one study to dysphagia following head and neck surgery, and one to individuals with dysphagia of mixed aetiology.

The results of international stakeholder surveys demonstrated the common use of regular food plus four to five levels of food texture modification for the management of swallowing problems across the age spectrum. A synthesis of the literature from the systematic review demonstrates broadly that solid, hard and adhesive (sticky) foods require an increased chewing rate, longer chewing duration and greater muscle effort. Pureed food requires the shortest chewing duration, least chewing and muscle effort. During normal chewing, the tongue and jaw move in a coordinated way to avoid injury from biting the tongue during chewing. This means, however, that there is no posterior tongue-to-palate seal during the chewing and oral processing of foods. This is in contrast to the pattern expected with liquids (Hiiemae & Palmer, 1999). It is not uncommon for particles of masticated food to collect in the pharynx, usually in the vallecular space, during oral preparation. Foods that require chewing do present a choking risk. Poor dentition and neurological conditions are consistently identified as risk factors for choking (Kennedy et al., 2014). In healthy people, regardless of the initial state of the food, after oral processing and at the point of swallow initiation, the bolus is a cohesive mass.

The paucity of research into the therapeutic use of food texture modification for dysphagia management means that the recommendations in this document regarding food texture are based on an understanding that altering food texture modification has demonstrated a therapeutic benefit for reducing the risk of choking. Recommendations regarding best practice are also based on clinical experience, surveys of reported practice patterns and expert opinion regarding the number of levels of food textures reported.

There is an urgent need to generate clear descriptions for different classes of chewable food, so that empirical evidence can be collected to demonstrate associated differences in oral processing and swallowing behavior.

Current and planned research

IDDSI is aware of current and planned research studies of general and clinical populations using IDDSI framework stimulus items. IDDSI looks forward to updating the Evidence as these studies are published.

Evidence for specific variables relating to different food textures and their accompanying grade of evidence (NHMRC, 2000) are shown in the table below. *Note,* despite best efforts, the list cannot be exhaustive, and will continue to evolve as a living document over time as further research is conducted and reported.

Variable	**Reference**	**Grade of Evidence**
Investigations of Levels 0 – Thin in the research literature	As noted in Steele et al. (2015): Barata et al., 2013 Binjie et al. , 2010 Bisch et al., 1994 Butler et al., 2004 Chen et al., 1992 Chi-Fishman & Sonies, 2002 dos Santos et al., 2011 Goldfield et al., 2013 Igarashi et al., 2010 Ishida et al., 2002 Lee et al., 2012 Lee et al., 2010 Lin et al., 2011 Linden et al., 1989 Newman et al., 2016 Oommen et al., 2011 Reimers-Neils et al., 1994 Ruark et al., 2002 Saitoh et al., 2007 Steele & Van Lieshout, 2004 Steele & Van Lieshout, 2005 Taniwaki et al., 2013 Troche et al., 2008 Youmans et al., 2009	III-2 IV III-2 III-2 IV IV IV III-2 IV IV IV IV IV IV IV III III-2 IV III-2 IV IV IV IV IV III-2
Evidence for existence of Level 1 – Slightly Thick in the research literature	Stuart & Motz , 2009 de Almeida et al., 2011 Cichero et al., 2011 September et al., 2014	In vitro bench test In vitro bench test In vitro bench test In vitro bench test
Investigations of Level 2 – Mildly Thick in the research literature	As noted in Steele et al. (2015): Barata et al. , 2013 Chen et al., 1992 Chi-Fishman & Sonies, 2002 Goldfield et al. 2013 Igarashi et al., 2010 Inagaki et al., 2008 Inagaki et al., 2009a Inagaki et al., 2009b Lee et al., 2010 Newman et al., 2016 Oommen et al., 2011 Reimers-Neils et al., 1994 Ruark et al., 2002 Steele & Van Lieshout, 2004 Steele & Van Lieshout, 2005 Youmans et al., 2009	III-2 IV IV IV IV IV IV IV IV IV III III-2 IV III-2 IV IV III-2

Variable	Reference	Grade of Evidence
Investigations of Level 3 – Moderately thick/Liquidised in the research literature	As noted in Steele et al. (2015): Butler et al., 2004 Chi-Fishman & Sonies, 2002 Igarashi et al., 2010 Inagaki et al., 2008 Inagaki et al., 2009a Inagaki et al., 2009b Steele & Van Lieshout, 2004 Steele & Van Lieshout, 2005 Youmans et al., 2009	III-2 IV IV IV IV IV IV IV IV III-2
Investigations of Level 4 – Extremely thick / Pureed in the research literature	As noted in Steele et al. (2015): Barata et al., 2013 Bingjie et al., 2010 Bisch et al., 1994 Butler et al., 2004 Chen et al., 1992 Chi-Fishman & Sonies, 2002 Dos Santos et al., 2011 Gisel, 1991 Inagaki et al., 2008 Inagaki et al., 2009a Inagaki et al., 2009b Ishida et al., 2002 Kim & Han, 2005 Lin et al., 2011 Newman et al., 2016 Reimers-Neils et al., 1994 Taniwaki et al., 2013 Troche et al., 2008 Youmans et al., 2009	III-2 IV III-2 III-2 IV IV IV III-2 IV IV IV IV IV III-2 IV III IV IV IV III-2
Drinks that are too thick increase the risk of post swallow residue in the pharynx	Hind et al., (2012) Newman et al. (2016) Robbins et al., (2008)	IV III II
Investigations of Level 5 – Minced & Moist In the research literature	Nil to date	
Investigations of Level 6 - Soft In the research literature	As noted in Steele et al. (2015): Anderson et al., 2002 Ashida et al., 2007 Funami et al., 2012 Ishida et al., 2002 Lee et al., 2012 Nagatomi et al., 2008 Taniwaki et al., 2013	III-2 IV IV IV IV IV IV IV
Investigations of Level 7 - Regular In the research literature	As noted in Steele et al. (2015): Anderson et al., 2002 Ashida et al., 2007	III-2 IV IV

Variable	Reference	Grade of Evidence
Investigation of Level 7 – Regular In the research literature contd.	Barata et al., 2013 Binjie et al., 2010 Chen et al., 1992 Hoebler et al., 1998 Ishida et al., 2002 Karkazis, 2002 Karkakazis & Kossioni, 1997 Karkakazis & Kossioni, 1998 Nagatomi et al., 2008 Ruark et al., 2002 Saitoh et al., 2007	IV III-2 IV IV IV IV IV IV IV III-2 IV
Investigations of Mixed consistency foods In the research literature	As noted in Steele et al. (2015): Kim & Han, 2005 Lee et al., 2012 Saitoh et al., 2007	III-2 IV IV IV
Investigations of Transitional Foods In the research literature	As noted in Steele et al., (2015): Gisel, 1991	III-2 III-2
	Dovey et al., 2013	IV
Investigations of foods that are a choking risk In the research literature	Berzlanovich et al., 1999 Chapin et al., 2013 Centre for Disease Control and Prevention, 2002 Japanese Food Commission, 2010 Kennedy et al., 2014 Morely et al., 2004 Mu et al., 1991 Rimmell et al., 1995 Seidel et al., 2002 Siddell et al., 2013 Wick et al., 2006	III-2 III-2 III-2 III-3 III-3 III-2 III-2 III-2 IV III-2 III-3
Investigations of food particle size and bite size In the research literature	Peyron et al., 2004 Woda et al., 2010 Archambault et al., 2010 Fotijn-Tekamp et al. 2004 Jalabert-Malbos et al., 2007	IV IV IV IV IV

Grading of evidence – National Health and Medical Research Council (2009)

I[a]	Evidence from systematic review of level II studies
II	Evidence from a randomized control trial
III-1	Evidence from well-designed pseudo-randomised controlled trials (e.g., alternate allocation or some other method)
III-2	Evidence from comparative studies with concurrent controls and allocation not randomised experimental trial; cohort studies, case-control studies, or interrupted time-series with a control group (i.e. non-consecutive cohort study)
III-3	Evidence from comparative studies without concurrent controls, historical control study, two or more single-arm studies, or interrupted time series without a parallel control group
IV	Evidence from case series, either post-test or pre-test and post-test, or superseded reference standards

[a]"A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence."

*Accompanying documents (http://iddsi.org/framework/):

- IDDSI Testing Methods
- IDDSI Evidence
- IDDSI Frequently Asked Questions (FAQs)

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