

Testing Methods and Evidence

Drinks: Levels 0-4

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 detailed descriptors for the 5 levels of drinks in the IDDSI Framework (Levels 0-4). Descriptors are supported by simple measurement methods that can be used by people with dysphagia or by caregivers, clinicians, food service professionals or industry to confirm the level of a drink.

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);

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

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.



Evidence and Measurement

Evidence

A systematic review of the literature was conducted to examine the impact of drink thickness and food texture on swallowing behavior across the age spectrum (Steele et al., 2015 Dysphagia, 30(1): 2-26).

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.

Measurement

Accurate measurement of fluid flow properties is a complex task. To date, both research and existing national terminologies, have studied or recommended the classification of drinks based on viscosity. However, viscosity measurement is not accessible to most clinicians or caregivers.

Furthermore, viscosity is not the only relevant parameter: the flow of a drink as it is consumed is influenced by multiple other variables including density, yield stress, temperature, propulsion pressure and fat content (O'Leary et al., 2010; Sopade et al., 2007, Sopade et al., 2008a,b; Hadde et al.2015a,b). The systematic review demonstrated wide variability in testing techniques used and found that other key parameters such as shear rates, sample temperature, density and yield stress were rarely reported (Steele et al., 2015; Cichero et al., 2013). Drinks thickened with different thickening agents may have the same measurement of apparent viscosity at one particular shear rate, and yet have very different flow characteristics in practice (Steele et al. 2015; O'Leary et al., 2010; Funami et al., 2012; Ashida et al., 2007; Garcia et al., 2005). In addition to variations in flow associated with drink characteristics, flow rates during swallowing are expected to differ depending on a person's age and level of impairment of swallowing function (O'Leary et al., 2010).

For these reasons, a measurement of viscosity has not been included in the IDDSI descriptors. Instead, a gravity flow test using a 10ml slip tip syringe has been chosen by IDDSI as a practical objective measure to classify drinks based on their rate of flow. The controlled conditions are broadly representative of drinking through a straw or beaker. Although the equipment is simple, it is already internationally standardised and the IDDSI Flow Test has been found to categorise a wide range of liquids reliably, in agreement with currently existing laboratory tests and expert judgement. It has been found to be sensitive enough to demonstrate small changes in thickness associated with change in serving temperature.

For extremely-thick drinks, which do not flow through a syringe in 10 seconds and are best consumed with a spoon, a Fork Test is recommended as a method for determining consistency.

Evidence relating to levels of thickness and an accompanying grading of evidence (NHMRC, 2000) is shown in the table below. *Note:* despite best efforts, this list is not exhaustive. We intend to continue to update this descriptors document over time as further research is conducted and reported.

| Variable | Reference | Grade of |
|----------------------------|--|---------------------|
| | | Evidence |
| Investigations of | As noted in Steele et al. (2015): | 1 |
| Levels 0 – Thin | | |
| in the research literature | Barata et al., 2013 | IV |
| | Binjie et al. , 2010 | 111-2 |
| | Bisch et al., 1994 | 111-2 |
| | Butler et al., 2004 | IV |
| | Chen et al., 1992 | IV |
| | Chi-Fishman & Sonies, 2002 | IV |
| | dos Santos et al., 2011 | 111-2 |
| | Goldfield et al., 2013 | IV |
| | Igarashi et al., 2010 | IV |
| | Ishida et al., 2002 | IV |
| | Lee et al., 2012 | IV |
| | Lee et al., 2010 | IV |
| | Lin et al., 2011 | IV |
| | Linden et al., 1989 | IV |
| | Oommen et al., 2011 | 111-2 |
| | Reimers-Neils et al., 1994 | IV |
| | Ruark et al., 2002 | -2 |
| | Saitoh et al., 2007 | IV |
| | Steele & Van Lieshout, 2004 | IV |
| | Steele & Van Lieshout, 2005 | IV |
| | Taniwaki et al., 2013 | IV |
| | Troche et al., 2008 | IV |
| | Youmans et al., 2009 | 111-2 |
| | | 111 2 |
| Evidence for existence of | Stuart & Motz , 2009 | In vitro bench test |
| Level 1 – Slightly Thick | de Almeida et al., 2011 | In vitro bench test |
| in the research literature | Cichero et al., 2011 | In vitro bench test |
| | September et al., 2014 | In vitro bench test |
| Investigations of | As noted in Steele et al. (2015): | 1 |
| Level 2 – Mildly Thick | | |
| in the research literature | Barata et al. , 2013 | IV |
| | Chen et al., 1992 | IV |
| | Chi-Fishman & Sonies, 2002 | IV |
| | Goldfield et al. 2013 | IV |
| | Igarashi et al., 2010 | IV |
| | Inagaki et al., 2008 | IV |
| | Inagaki et al., 2009a | IV |
| | Inagaki et al., 2009b | IV |
| | Lee et al., 2010 | IV |
| | Oommen et al., 2011 | 111-2 |
| | Reimers-Neils et al., 1994 | IV |
| | Ruark et al., 2002 | 111-2 |
| | Steele & Van Lieshout, 2004 | IV |
| | Steele & Van Lieshout, 2004 Steele & Van Lieshout, 2005 | IV IV |
| | Youmans et al., 2009 | III-2 |
| | 100mans et al., 2005 | 111-2 |

| al., 2004 nan & Sonies, 2002 et al., 2010 t al., 2008 t al., 2009a t al., 2009b an Lieshout, 2004 Van Lieshout, 2005 et al., 2009 in Steele et al. (2015): : al., 2013 : al., 2010 al., 1994 al., 2004 al., 1992 nan & Sonies, 2002 os et al., 2011 | IV IV IV IV IV IV IV IV III-2 III-2 IV IV IV IV IV IV III-2 |
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| in Steele et al. (2015): al., 2013 al., 2010 al., 1994 al., 2004 al., 1992 nan & Sonies, 2002 | I IV III-2 III-2 IV IV IV |
| al., 2013 al., 2010 al., 1994 al., 2004 al., 1992 nan & Sonies, 2002 | IV III-2 III-2 IV IV IV |
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| al., 2002 | IV |
| ın, 2005 | 111-2 |
| 2011 | IV |
| Neils et al., 1994 | IV |
| et al., 2013 | IV |
| t al., 2008 | IV |
| et al., 2009 | III-2 |
| l., (2012) | IV |
| (2000) | П |
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Grading of evidence – National Health and Medical Research Council (2000)

| I | Evidence from systematic review of all relevant randomised controlled trials |
|-------|---|
| 11 | Evidence from at least one properly designed randomised controlled trial, retrospective studies |
| III-1 | Evidence from well-designed pseudo-randomised controlled trials (e.g., alternate allocation or some other method) |
| 111-2 | Evidence from comparative studies with concurrent controls and allocation not randomised (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 with historical control, 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 |





| Description/ Characteristics | Flows like water Fast flow Can drink through any type of teat/nipple, cup or straw as appropriate for age and skills |
|--|--|
| Physiological rationale for this level of thickness | Functional ability to safely manage liquids of all types |
| Testing method IDDSI Flow Test* | • Test liquid flows through a 10 mL slip tip syringe completely within 10 seconds, leaving no residue (see IDDSI Flow Test instructions*) |





| Description/ | Thicker than water Requires a little more effort to drink than thin liquids Flows through a straw, syringe, teat/nipple Similar to the thickness of commercially available |
|--|--|
| Characteristics | 'Anti-regurgitation' (AR) infant formula |
| Physiological rationale for this level of thickness | Predominantly used in the paediatric population as a thickened drink that reduces speed of flow yet is still able to flow through an infant teat/nipple. Consideration to flow through a teat/nipple should be determined on a case-by-case basis. |
| Testing method | Test liquid flows through a 10 mL slip tip syringe leaving 1-4 mL in |
| IDDSI Flow Test* | the syringe after 10 seconds (see IDDSI Flow Test instructions*) |





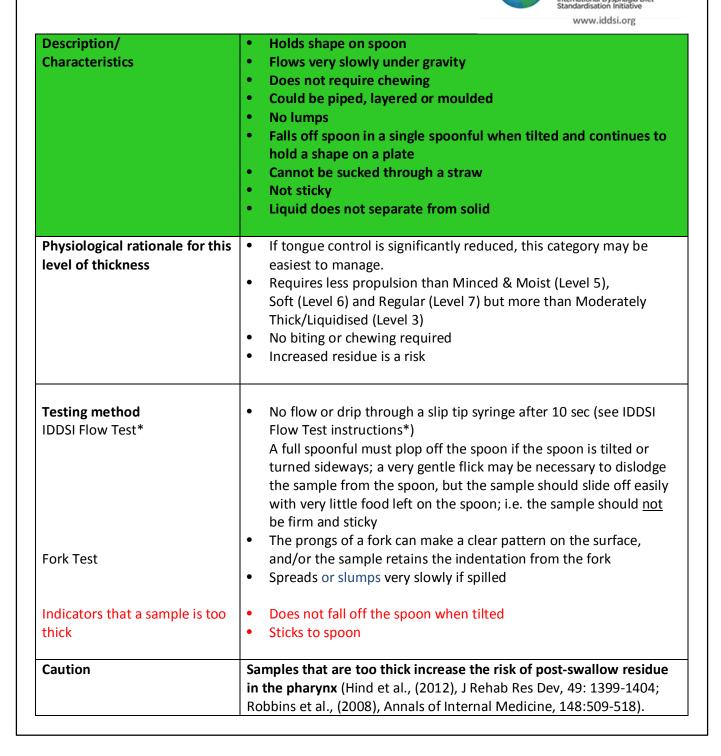
| Description/ Characteristics | Flows off a spoon Sippable, pours quickly from a spoon, but slower than thin drinks Effort is required to drink this thickness through standard bore straw (standard bore straw = 0.209 inch or 5.3 mm diameter) |
|--|--|
| Physiological rationale for this level of thickness | If thin drinks flow too fast to be controlled safely, these Mildly Thick liquids will flow at a slightly slower rate May be suitable if tongue control is slightly reduced. |
| Testing method IDDSI Flow Test* | • Test liquid flows through a 10 mL slip tip syringe leaving 4 to 8 ml in the syringe after 10 seconds (see IDDSI Flow Test instructions*) |

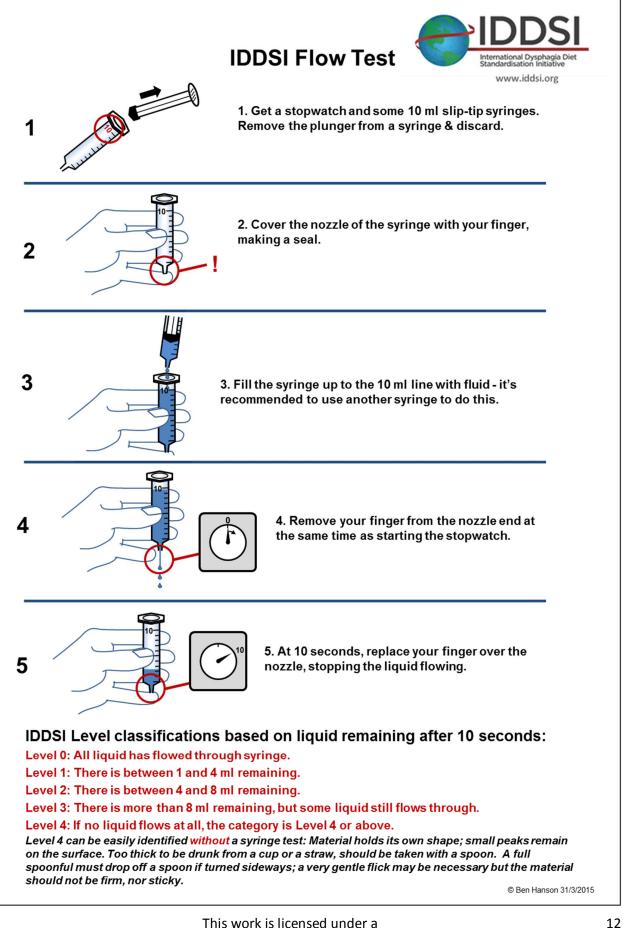
3 MODERATELY THICK JUDDISED

| Description/ | Will not hold shape its shape on a spoon Sippable, pours slowly off a spoon Difficult to suck through a standard bore or wide bore straw |
|------------------------------------|--|
| Characteristics | (wide bore straw = 0.275 inch or 6.9mm) Cannot be piped, layered or moulded Cannot be eaten with a fork because it drops through the prongs |
| Physiological rationale for this | If tongue control is insufficient to manage Mildly Thick drinks |
| level of thickness | (Level 2), this Moderately Thick/Liquidised level may be suitable Flows slowly from a spoon or cup: easier to control Allows more time for oral control Needs some tongue propulsion effort |
| Testing method IDDSI Flow Test* | Test liquid flows slowly through a 10 mL slip tip syringe leaving more than 8 mL in the syringe after 10 seconds (see IDDSI Flow Test instructions*) |
| Fork Test | Prongs of a fork do not make a clear pattern on the surface Spreads out if spilled |

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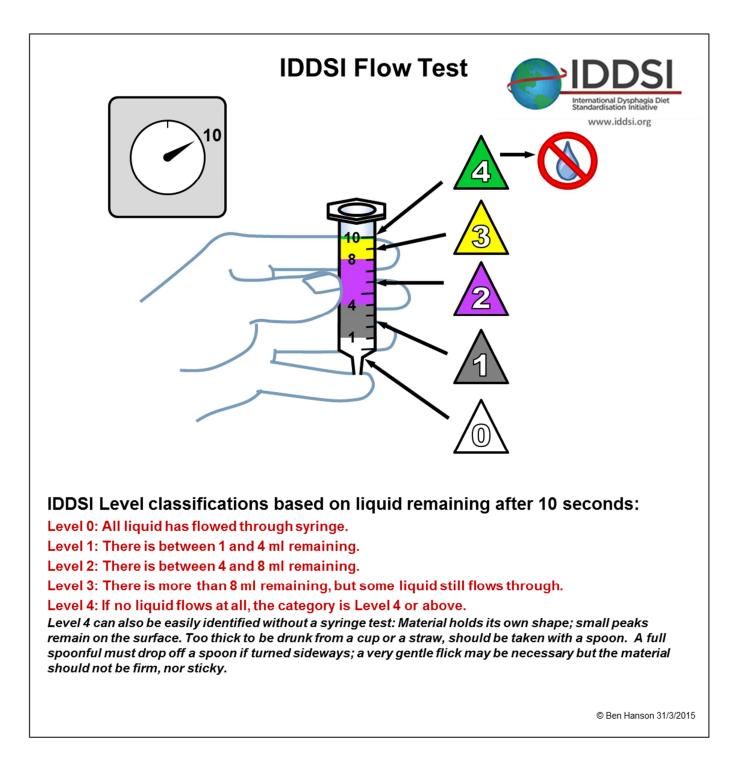
EXTREMELY THICK PUREED





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Q: My facility only uses two levels of drink thickness; do we have to use all of the IDDSI drink thickness levels?

A: No, although the IDDSI framework includes five different levels of increasing drink thickness, there is no expectation that every facility will use all five levels. For example, some aged care facilities may only use Level 0 -Thin, Level 3- Moderately Thick/Liquidised and Level 4 – Extremely Thick/Pureed. By labeling the drinks in this way, when a patient/client moves from a facility with fewer drink levels to a hospital with more drink levels, it will be faster, safer and more accurate for health professionals and care staff to provide the appropriate drink thickness level.

Q: I've not heard of Level 1 – Slightly Thick before, what is this level?

A: Level 1 – Slightly Thick is predominantly used by paediatric clinicians and refers to the thickness level similar to commercially prepared anti-regurgitation infant formula. It is noticeably thicker than regular Level 0 – thin drinks, but thinner than Level 2 – Mildly Thick drinks. It is thick enough to slow the flow rate through a teat/nipple, whereas Level 2 – Mildly thick fluids are too thick to flow through a teat/ nipple. Clinicians working with adult caseloads may find that some products that they have previously described as "naturally thick" fall in this Level 1 – Slightly Thick category.

Q: My facility has used the terms 'nectar' and 'honey' for decades; why weren't these terms used in the IDDSI framework?

A: Two international stakeholder surveys were conducted encompassing more than 5000 responses. Although the terms 'nectar' and 'honey' were widely understood in some parts of the world, they had no meaning in other parts of the world, particularly Asia. Other considerations included the natural variability of 'honey' in its crystalline and liquid states, and that that the food honey is a botulism risk for infants under the age of 12 months. As an international framework suitable for use across the age spectrum, it was decided that terms that described variations of drink thickness would be most appropriate.

Q: Why are 'Liquidised' foods and 'Moderately thick' drinks on the same level and why are 'Extremely thick' drinks and 'Pureed' foods on the same level?

A: When viewed from a drink thickness perspective, regardless of whether an item is a food (e.g. liquidised soup), or a drink (e.g. moderately thick liquid), the texture and flow characteristics are very similar. The IDDSI framework demonstrates this equivalence in texture, regardless of whether these items would conventionally be referred to as 'food' or 'drinks'.

Q: Won't fruit smoothies and liquidised soups clog up the syringe?

A: The official IDDSI recommendation is that products in Levels 0-4 should be smooth and homogenous, without particles or lumps. If you are blending a smoothie, then you must take care to ensure there are no lumps or seeds. If particles clog the syringe, then additional blending or passing through a sieve is recommended.

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Q: What does a 10 mL Slip Tip syringe look like and can I be sure it is the same around the world?

A: A 10 mL 'slip tip' syringe is shown in the photo below. It is sold as a plastic sterile hypodermic syringe for single use. It is also known as a 'Luer slip tip' syringe. The tip of the syringe is smooth and without a locking system. It does not matter if the tip is situated to be central or eccentric (positioned off to one side). The slip tip hypodermic syringe is manufactured to international standards (ISO 7886-1) to ensure that it is the same around the world. The syringes come in different capacities (e.g. 1 mL, 5 mL, 10 mL, 20 mL etc.). We have chosen the 10 mL syringe to be used for the IDDSI Flow test. Before use, check the nozzle is clear and free from any plastic residue or manufacturing defects that very occasionally occur. A very quick way to check is to ensure that 10ml of water flows completely through the syringe within 10 seconds using the IDDSI Flow test instructions.



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