

Levels of abstraction in the registerial adaption of specialized medical information for lay readerships: An SFL-based inquiry

Aage Hill-Madsen, Aalborg University

Abstract: Situated within LSP (Languages for Specific Purposes) linguistics and knowledge communication research, the present article investigates three cases of intergeneric rewriting, all of them within the field of healthcare. In each of these cases, an expert-oriented text containing specialized medical and/or pharmaceutical information is rewritten into a (shorter) text aimed at a lay target audience, providing those items of information that are relevant for the lay reader in the role of, e.g., patient or clinical trial participant. The rewriting, in other words, involves registerial adaptation in terms of field specialization and tenor. The three pairs of genres investigated were: 1) A specialized clinical trial protocol as ‘source’ text and the Participant Information Sheet as ‘target’ text, 2) A pharmaceutical Summary of Product Characteristics (concerned with a specific medicinal product) as ‘source’ and the Patient Information Leaflet as ‘target’, and 3) a scientific review of clinical literature (concerned with two specific types of medical intervention) as ‘source’ and a lay summary of the review as ‘target’. The investigation, which is theoretically based on SFL register theory, focuses on a particular semantic aspect of the rewriting, namely shifts between the texts as a whole in terms of their level of abstraction/concreteness. The investigation proceeded from the assumption that the rewriting for lay target readerships would be accompanied by a semantic ‘move’ towards greater concreteness. The actual findings, however, revealed considerably more nuance, with only one of the lay-oriented genres (the Patient Information Leaflet) actually representing greater concreteness in meanings in comparison with the specialized ‘source’ text. In one other case (the Information Sheet for clinical trial participants), the semantic profile more or less matched that of the ‘source’ text, and in the final pair the ‘target’ text (the lay summary of the scientific review) turned out to represent an increase in the level of abstraction.

Keywords: Medical genres, registerial adaptation, semantic stratum, levels of de/contextualization, Systemic Functional Linguistics

1. Introduction

For the last quarter of a century, healthcare systems in the Western world have become increasingly aware of the importance of patient engagement and patient-centred care. This means that instead of (sparse) one-way communication from doctors to patients, healthcare has become, or is becoming, “a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care” (Carman et al. 2013: 223-224). According to Coulter & Ellins (2007) and Epstein & Street (2008), the principle of patient engagement improves the quality of healthcare, leading to better treatment outcomes. From the perspective of linguistics and knowledge communication research, the particular element of interest in the overall principle of patient engagement is patient education, which inevitably involves the mediation of knowledge across a knowledge asymmetry (see Pilnick 1998; Kastberg 2011). Thus, the present article, which is theoretically underpinned by SFL register and genre theory (Halliday 1978; Halliday & Hasan 1989; Martin 1992; Hasan 1999), is a qualitative study of a particular semantic aspect associated with the recontextualization of specialized knowledge for lay target readerships. Specifically, the article explores the rewriting of specialized medical texts into summarized versions for a non-expert audience. Given the change of readership, the rewriting involves a registerial transformation, especially in the degree of specialization and tenor. While previous research on this type of rewriting has charted shifts in meanings and lexicogrammar related to technicality and tenor (e.g., Hill-Madsen, 2015a, 2015b, 2022b), no research to date has

explored shifts in meanings related to levels of abstraction/concreteness. Analytically, the investigation specifically relies on the framework formulated by Hasan et al. (2007; see also Cloran 2010), which identifies a scale of semantic categories ranged according to degrees of context-dependence (a scale to be referred to henceforth as the *cline of abstraction*), with highly context-dependent, or ‘concrete’, meanings at one end of the cline and highly abstract and context-independent meanings at the other end (for an elaboration of the specific semantic categories of the cline, see Section 2.2).

While the study is not a quantitative one based on a large-scale corpus and thus not one that allows actual hypothesis testing, the inquiry nevertheless proceeded from a certain assumption. At the outset of the investigation, it was assumed that the shift from an expert to a lay target readership could be expected to correlate with a ‘movement’ towards a higher degree of ‘concreteness’. However, since the inquiry is a qualitative one based on a small set of data, the actual research aim is to explore, in three pairs of genres (specialized ‘source’ texts and the derived, lay-oriented ‘target’ texts – see Section 2), what *types of change* in levels of abstraction accompany the genre transformations.

2. Theoretical underpinnings and analytical framework

2.1. The register and genre theory of SFL

One of the core tenets of SFL as a socio-semiotic theory of language is the inextricable link between language and social context (e.g. Halliday 1978; Halliday & Hasan 1989). Contextual embeddedness pertains to language as a system as well as language in actual use (language as *instance* or *text*): From the systemic perspective, in the words of Halliday (1973: 34), “[t]he internal organization of natural language can best be explained in light of the social functions which language has evolved to serve,” or, “[l]anguage is as it is because of what it has to do” (Halliday 1978: 19). From the perspective of language in actual use, specific instances of linguistic communication will always function within some kind of social context. Only by serving some kind of real-life purpose within some kind of communicative situation is the act of ‘linguaging’ able to fulfill its semiotic purpose, i.e., to *make sense*. Only in this way can specific instances of ‘linguaging’ become *text* (see, e.g., Halliday & Hasan 1976; Eggins 2004).

Nowhere else has the notion of situational context been theorized more thoroughly than in SFL (e.g., Halliday & Hasan 1989; Hasan 1995, 1999, 2014). Definitions have evolved over the last half century, and definitional disagreements do exist within the SFL community (most notably between the original conception represented by Halliday & Hasan (e.g., 1989) and Martin’s interpretation (e.g., 1992; Martin & Rose 2008). Nevertheless, there is general agreement about the notion of situational context as a triadic construct consisting of the three dimensions or variables *field*, *tenor* and *mode*: In short, field is concerned with the social activity in which the ‘linguaging’ plays a part (figuring as ‘subject matter’ in self-contextualizing texts); tenor refers to the role relationship enacted by the communicants; and mode refers to the role played by language in the situation. In Martin’s (1992) and Martin & Rose’s (2008) interpretation (to be followed here), one further semiotic level located ‘above’ the field-tenor-mode triad is that of genre, concerned with the overall social purpose of the communicative event.

The theoretical impetus behind the present investigation is Hasan’s observation that

[t]he contextual parameters – field, tenor and mode – are not, to use Bernstein’s (1975) terminology, three strongly classified [i.e. separate] domains, each with a clear-cut boundary of its own: they are in fact permeable. What choices are made in field is relevant to some extent to the choices in tenor and in mode. (Hasan 1999: 244)

To illustrate the ‘permeability’ referred to by Hasan, one may point to typical communicative situations in the healthcare sector, i.e., where the role relationship is defined as ‘doctor-to-patient’. This type of tenor will almost inevitably be accompanied by a certain field, viz., subject matters like ‘disease’ and ‘medication’. Further, as mentioned in the introductory section, the present study proceeds from the expectation that the lay-oriented tenor of the texts to be investigated may have implications for the texts’ overall positioning on the cline of abstraction, with a ‘movement’ towards greater ‘concreteness’ to be expected. This, at least, would be consistent with the style advocated by the European Commission in its official guidelines for *Good Lay Summary Practice*:

A fundamental principle when addressing a lay audience is using **conversational, everyday language** and avoid formal, medical jargon. In practice, this means to “write the way you talk.” Most people do not read or write much and writing in conversational style can be a means of reaching out to them. (Directorate-General for Health and Food Safety 2021: 35 [*my emphasis*]).

A preliminary expectation is that the “conversational, everyday language” advocated in the above quote equals low levels of abstraction and, conversely, a high degree of concreteness.

In terms of interstratal ‘hook-up’, it is to be noted that the semantics of the cline of abstraction is here regarded as being independent of any specific contextual variable. Rather, in line with the ‘permeability’ hypothesis referred to above, the semantics of concreteness/abstraction has implications for more than one variable (see the analyses in Section 4) and for the stratum of genre also.

2.2. Analytical framework: The semantic cline of abstraction

As already mentioned, the semantic cline of abstraction will here be operationalized by means of the framework proposed by Hasan et al. (2007) and Cloran (2010). The framework’s categories represent varying strengths of context-dependence¹ in linguistic utterances or speech acts (termed *rhetorical units* (RUs) and grammatically realized in clauses). This means that the framework’s 11 categories² are ranged on a continuum according to their embeddedness in/distance from the ‘here-and-now’ of the communicative exchange. Maximum context-dependence is here equated with a high level of concreteness, and the highest degree of context-independence is equated with the opposite, i.e., a high level of abstraction. The cline is the following (Fig. 1 below).

Figure 1: A cline of RU types (adapted from Hasan et al. 2007: 724).

Action . Commentary . Reflection . Observation . Report . Recount . Plan . Prediction . Account . Conjecture . Generalization


The distinguishing characteristics of each category are two semantic features combined: the type of *Central Entity* (CE) (grammatically the Subject of a ranking clause) and the type of *Event Orientation* (EO) (a feature of the grammatical Verb). Types of CE are differentiated according to their proximity to/remoteness from the ‘here’ of the communicative event, yielding the following taxonomy:

¹ It should be mentioned that the semantic framework that is here termed *the cline of abstraction* appears to be to some degree parallel to Maton’s (2013, 2014: ch. 6; see also Hill-Madsen 2022a, 2025) concept of *semantic gravity* – a semantic variable similarly concerned with degrees of context-dependence or ‘concreteness’.

² The following account is based on Hill-Madsen (2022a).

- 1) Interactant (speaker/listener)
- 2) Co-present person/object
- 3) Absent person/object
- 4) Generalized person/object.

EO types are differentiated according to their closeness to/remoteness from the ‘now’ of the speech event in terms of:

- Time: The event or action may be either a) **concurrent** with the ‘now’ (= close to ‘now’) or b) **prior**, i.e., situated in the past (= remote).
- Habituality: The event or action may be a) **non-habitual**, i.e., located in time (= close) or b) **habitual**, i.e., timeless (= remote).
- Realis/irrealis: The event or action may be a) **real** (= close) or b) **imagined**, e.g., forecast or hypothetical (= remote).

The 11 semantic categories on the cline of abstraction are defined by the following combinations of values (adapted from Hasan et al. 2007: 722):

Table 1: Types of rhetorical units defined and exemplified. Examples are taken from Hill-Madsen (2025).

	Type of Central Entity	Type of Event Orientation	Examples
1. Action	Interactant	proposal (i.e., command)	<i>Remember to take your medicine!</i>
2. Commentary	Interactant	concurrent, non-habitual	<i>You're looking pale and ill today.</i>
3. Reflection	Interactant	concurrent, habitual	<i>As a patient, you have certain responsibilities for your own health.</i>
4. Observation	co-present person/object	concurrent, habitual	<i>[Pharmacist handing a patient/customer a package of medicine:] This medicine may have some unpleasant side effects.</i>
5. Report	absent person/object	concurrent, non-habitual	<i>[Pharmacist to patient/customer:] The side effects are listed in the information leaflet.</i>
6. Recount	[all types]	prior, i.e., situated in the past	<i>The clinical trials found a number of side effects associated with the drug.</i>

7. Plan	Interactant	forecast, non-hypothetical, volitional	<i>[Doctor to patient:] I'll call the hospital later and book an appointment for you.</i>
8. Prediction	co-present, absent or generalized person/object	forecast, non-hypothetical, non-volitional	<i>[Pharmacist to patient/customer:] You will be rather certain to experience some not-so-pleasant side effects.</i>
9. Account	absent person/object	concurrent, habitual	<i>[Patient to doctor:] My wife always reminds me to take my medication, so that's how I remember.</i>
10. Conjecture	[all types]	forecast, hypothetical	<i>[Doctor to patient:] If you don't lose weight, your heart may suffer.</i>
11. Generalization	generalized person/object	concurrent, habitual	<i>The primary function of the immune system is to protect the body from disease.</i>

3. Methods and materials

As mentioned in the introductory section, the article investigates three different specialized genres within the field of medicine/pharmacy, for each of which a summarized version also exists. Each of these summaries constitutes an independent genre, aimed at a different target readership, viz., lay readers. Since the aim of the study is to establish a “qualitative profile” (Patton 2002: 236) of the rewriting of these three genres (specifically in terms of the semantic shifts occurring along the *cline of abstraction*), the sampling technique applied was the one termed *typical case sampling* (Patton 2002: 236). Accordingly, three ‘pairs’ of texts (specialized ‘source’ text and derived, lay-oriented ‘target’ text) deemed representative of each genre were sampled. A point of commonality between the three pairs is the medical condition they all three are concerned with, wholly or partly, which is heart problems. The genres are the following:

- *Clinical trial protocols and participant information sheets*: As part of the preparation process for a clinical trial, researchers are required to provide a protocol of the prospective trial for approval by the relevant health authorities. The protocol specifies the intervention to be tested, the type of condition targeted by the intervention and the overall study design, including aspects like participant population and the methods for assessing the efficacy of the intervention. The lay-oriented, and shortened, version of the trial protocol is the so-called *Participant Information Sheet* (PIS), which provides the information about the trial relevant for the participants (i.e., patients).³ The text pair was sampled from the EU’s clinical trials register,⁴ and the title of the trial in question is “An Open-Label Extension and Safety Monitoring Study of Acoramidis (AG10) in Participants with Symptomatic Transthyretin Amyloid Cardiomyopathy Who

³ The list of contents for each of the sampled texts are reproduced in Appendices A and B, respectively.

⁴ <https://euclinicaltrials.eu/>.

Completed the Phase 3 ATTRIBUTE-CM Trial (AG10-301)” (Eidos 2023a, 2023b).

- *Summaries of Product Characteristics* (source) and *Patient Information Leaflets* (target): In the EU, pharmaceutical companies applying for marketing authorization of a medicinal product are required to submit a *Summary of Product Characteristics* (SmPC) setting out the clinical and pharmaceutical particulars of the product, i.e., the condition targeted by the drug, method of administration (how to take it), dosage, how the drug works, its chemical composition, etc. The *Patient Information Leaflet* (PIL) provides those parts of the information from the SmPC that are relevant to the end consumer, with particular attention given to method of administration, precautions to be taken, and potential side effects of the drug.⁵ The text pair in question was sampled from the register of medicinal products published by the EU’s medicines regulator, the European Medicines Agency (EMA).⁶ The two texts (published as two different parts of the same document) are concerned with the product named *Dapagliflozin Viatris* (EMA 2023).
- *Cochrane reviews* and lay summaries:⁷ The source texts in this genre are systematic reviews of clinical literature concerned with specific types of medical therapies/interventions. The rewritten texts for the lay public are plain-language summaries occurring near the beginning of the specialized review text. The text (pair) sampled for present purposes was Kukendrarajah et al. (2024), entitled “External electrical and pharmacological cardioversion for atrial fibrillation, atrial flutter or atrial tachycardias: a network meta-analysis,” i.e., a comparative review of the results of trials investigating two different kinds of intervention (one using electrical impulse and one using medication) targeting certain abnormalities in heart rhythm.⁸

In terms of analytical methodology, the investigation is a comparative register analysis. All ranking clauses in all six texts were manually analysed and coded by the present author using the semantic framework set out in Subsection 2.2. In Section 4, the two texts in each text pair will be compared statistically to identify ‘movements’ along the cline of abstraction between the two texts as a whole, and sample analyses will be given.

4. Analytical results

4.1. The Eidos Clinical Trial Protocol

Of all six texts investigated, the clinical trial protocol is the only one that is almost exclusively situated in the most de-contextualized (or ‘most abstract’) half of the cline of abstraction, with only a very small percentage of Rhetorical Units (RU) in the other half, of which all (10 occurrences) represent Action. The statistics are:

⁵ The list of contents for each of the sampled texts are reproduced in Appendices C and D, respectively.

⁶ <https://www.ema.europa.eu/en/medicines>.

⁷ The reviews are published in the online *Cochrane Library* (<https://www.cochranelibrary.com/>).

⁸ The list of contents for the sampled source text is reproduced in Appendix E.

Table 2: Quantitative results for the Eidos clinical trial protocol.

Category	n	%
Generalization	68	14.1
Conjecture	86	17.9
Account	65	13.5
Prediction	232	48.2
Plan	0	0
Recount	19	4.0
Report	0	0
Observation	0	0
Reflection	0	0
Commentary	0	0
Action	10	2.1

In the following, only the four top categories on the scale will be commented on, being those (only) with some significant representation in the text. Apart from these, the Action category will also be exemplified, due to its significance as the only category represented from the ‘lower’ half of the abstraction cline.

As the statistics in Table 1 show, a minor, yet significant, number of RUs (14.1%) are Generalizations, around a third of which occur in the ‘Background’ section of the document, where the general characteristics of the medicinal product being investigated, named *Acoramidis*, are provided, as well as the defining characteristics of the condition targeted by the product, the disease named *transthyretin amyloidosis* (abbreviated as *ATTR* in the text):

- (1) *Clinically, ATTR presents as either a cardiomyopathy (ATTR-CM), an infiltrative, restrictive cardiomyopathy characterized by progressive left and right heart failure, or as a peripheral polyneuropathy (ATTR-PN), a length-dependent neurodegenerative disease affecting sensorimotor and autonomic functions.* (Eidos 2023a: 13)⁹

Example (1) features three Generalization RUs, of which the first is the main clause *Clinically, ATTR presents as either a cardiomyopathy (ATTR-CM) ... or as a peripheral polyneuropathy (ATTR-PN)*, with the generalized entity *ATTR* (the condition as a generalized phenomenon or concept) as Central Entity (CE) and the semantically timeless *presents* as the Event Orientation (EO). The two strings *an infiltrative, restrictive cardiomyopathy characterized by progressive left and right heart failure* and *a length-dependent neurodegenerative disease affecting sensorimotor*

⁹ CEs and EOs will be underlined in all examples, though not necessarily commented on in all cases.

and autonomic functions are here interpreted as two elliptical, non-restrictive relative clauses, or, in SFG terms, hypotactic clauses of elaboration (see Halliday & Matthiessen 2014: 464). In the two clauses, Subject and Finite are ellipsed but in both cases inferable as *which is*. As in the main clause, the implicit Finite (EO) is timeless, and the relative pronoun that in both cases would constitute an explicit CE would refer back to generalized phenomena/conditions (*cardiomyopathy* and *peripheral polyneuropathy*, respectively).

However, though concentrated in the ‘Background’ section, Generalization RUs occur throughout the document, typically providing specification or definition of a concept where needed, as in:

- (2) *Permanent sterilization methods include hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause and has to be confirmed with plasma FSH.* (Eidos 2023a: 22)

The first sentence subclassifies the generalized phenomenon of *permanent sterilization methods*, and the second defines the concept of *postmenopausal state*.

More frequent than Generalization are the two closely connected RU categories Conjecture and Prediction, accounting for 17.9% and 48.2% of RUs, respectively, i.e., altogether around two thirds of the text. The frequencies bear witness to the fact that the clinical trial protocol is a future-oriented genre, laying out the minutiae of an investigation that, at the time of writing, has yet to be carried out. Thus, it is no surprise that half the text consists of the RU type Prediction, as in the following examples:

- (3) *Participants will be provided with information on the method(s) of contraception acceptable for the study as a part of informed consent and will confirm that they understand the requirement to avoid pregnancy during the study and continue for 30 days after the last dose of IMP. Pregnancy tests will be performed during the study according to the Schedule of Assessments (Appendix A), and participants will receive guidance on avoidance of pregnancy throughout the study.* (Eidos 2023a: 22)

Example (3) consists of four RUs in which the CE is either a class-exhaustive entity (*Participants*, with the implicit qualification *in the trial*) or an ‘absent object’, viz., *pregnancy tests*, and the EO, realized by the Finite *will*, is in all cases ‘forecast’, ‘non-hypothetical’ and ‘non-volitional’.

It may be noted that the category of Prediction includes modulated propositions, as in the following example:

- (4) *Study participants should be reminded at the study visits regarding the consistent and correct use of protocol-specified contraception methods.* (Eidos 2023a: 23)

In Example (4), the EO is realized by the modal verb *should*, which, in terms of interpersonal semantics, is to be interpreted as an ‘obligation’. However, since the RU-category framework does not take interpersonal meaning into account, but is only concerned with the question of concreteness/abstraction (see above), the message in this case must be assigned to the Prediction category, since the RU, like those in Example (4), concerns non-hypothetical, future happenings, albeit ones *mandated* rather than simply predicted by the Sender of the text.

As already pointed out, the Prediction RU category is semantically closely related to Conjectures, in so far as both are concerned with future happenings. Conjectures, however, feature a hypothetical element which, in the clinical trial protocol, manifests itself in conditional statements

like the following:

- (5) [β] *If the participant has a need for a walking aid (e.g., cane) or supplemental oxygen at the Day 1 assessment, [α] it must be used consistently at each subsequent 6MWT throughout the study.* (Eidos 2023a: 29)

In Example (5), the conditional *If* initiating the β -clause conjures up a *possible*, or ‘hypothetical’, future situation, meaning that both clauses must be assigned to the Conjecture category. Most RUs categorized as Conjecture in the text have this type of realization, i.e., through the presence of a conditional dependent clause.

The only other RU category represented to some significant extent in the clinical trial protocol is Account, as in the following example:

- (6) [*Primary objectives are*] [[[*t*]/o assess safety and tolerability of acoramidis in participants with symptomatic transthyretin amyloid cardiomyopathy (ATTR-CM)]]]. (Eidos 2023a: 3)

Around a third of instances (23 out of 65) occur in the section entitled “Study objectives and endpoints”, specifying the research aims of the trial. In the document (Eidos 2023a: 15), the objectives are tabulated, with clauses like the embedded one in Example (6) (indicated above, in accordance with SFG notation, by the double square brackets) listed as bullet points, and the words *Primary* and *objectives* figuring in separate boxes. Example (6) is thus a purely linguistic rendering of the semiotics of the table. In the reconstructed sentence, the CE *Primary objectives* must be interpreted as an ‘absent object’ and the implicit EO (*are*) as ‘concurrent’ but not located in time, i.e., ‘habitual’ or timeless.

The final RU category to be commented on is Action, instantiated only 10 times in the text. Most of these messages are directives (with the grammatical verb in the imperative, as in example (7) below) relating to reporting duties in connection with the trial:

- (7) *For questions on SAE or pregnancy reporting, contact the above email address.* (Eidos 2023a: 34)

4.2. Eidos Participant Information Sheet

For the *Participant Information Sheet* (PIS) derived from the trial protocol, the statistics are the following:

Table 3: Quantitative results for the Eidos Participant Information Sheet.

Category	n	%
Generalization	19	3.4
Conjecture	230	41.7
Account	22	4.0
Prediction	226	41.0
Plan	0	0
Recount	17	3.1
Report	1	0.2
Observation	1	0.2
Reflection	7	1.3
Commentary	3	0.54
Action	25	4.5

The statistics reflect an overall distribution among RU classes that is very similar to that of the trial protocol document, in so far as in both documents the vast majority of messages belong to the ‘upper’ half, i.e., the most de-contextualized/abstract end of the abstraction cline. Unlike in the trial protocol, all categories in the ‘lower’ half are actually represented, but in such insignificant numbers that the instances do not warrant any further comment. Only the Action category, owing to its slightly higher representation, will be considered.

Like the *protocol* document, the PIS features a number of Generalization RUs providing background knowledge about the drug that is being tested and about the disease targeted by the drug. The proportion of Generalization RUs, however, is considerably lower (3.4% in the PIS vs. 14.1% in the *protocol*). A PIS example is:

- (8) *ATTR-CM occurs when a protein, called transthyretin, clumps together in the blood and accumulates in the heart. This accumulation in the heart is called amyloidosis.* (Eidos 2023b: 3)

The CEs (*ATTR-CM*, *a protein*, *This accumulation in the heart*) are all generalized entities, and the EOs (*occurs*, [*is (called)*], *clumps*, *is*) are in all cases timeless. It may be noted that, as in other genres communicating specialized knowledge to lay readers, part of this knowledge communication consists in ‘labelling’ or ‘naming’ (cf. Maton & Doran 2017), as in *called transthyretin* and ... *is called amyloidosis*. In terms of pragmatic or rhetorical value, such clauses may be considered didactic ones, in so far as they communicate field-specific *conceptual* knowledge, by introducing the relevant specialized *terms* to readers (here: *transthyretin* and *amyloidosis*) coupled with their meaning (see Hill-Madsen 2022a, 2025; Hill-Madsen & Pilegaard 2019). Thus, in the above

example the meaning of the term *amyloidosis* is defined as the accumulation, or ‘clumping together’, of the protein transthyretin in the heart.

As the statistics show, the two most frequent RU categories in the PIS are Conjecture and Prediction, together accounting for more than 80% of the text. Examples of Prediction are:

- (9) *Approximately 5 teaspoons [of blood] will be taken from you for clinical laboratory tests. These tests will include a measure of the levels of a protein in your blood called prealbumin.* (Eidos 2023b: 5)

In both sentences, the decisive factor for Predictions, viz., an EO denoting a ‘forecast’, ‘non-hypothetical’ event, is realized in the future-oriented modal verb *will*. Both clauses are Predictions and not Conjectures, being neither hypothetical nor conditional in any way. Thus, albeit addressed to the individual reader (*you, your*), the two clauses apply to all participants, all of whom will have a blood test. Conjectures, on the other hand, are messages containing some kind of hypothetical element. As in the source text (the *protocol* document), one manifestation of ‘hypothetical’ meaning is here taken to consist in conditionality, as in the following examples:

- (10) [1] *You will be asked to provide a urine sample,* [2a] *and a pregnancy test on your urine will be done* [2b] *if you are a female who could become pregnant.* (Eidos 2023b: 7)

While the message in the 1-clause is Prediction, applying to any reader unconditionally and thus forecasting a certain future event, the 2-clause complex is a conditional one ([2b] *if ...*), making their messages hypothetical ones (‘hypothetically, you are a woman of child-bearing age, and thus hypothetically you will have a pregnancy test done’).

Interestingly, the PIS features a considerably higher percentage of Conjecture RUs than its source, the *protocol* document (41.7% vs. 17.9%), and a slightly lower percentage of Prediction RUs (41.0% vs. 48.2%). The reason is that the specialized *protocol* document is written in the 3rd person and is concerned with the measures to be taken regarding the participant cohort as a whole but is also concerned with the special measures to be taken with subgroups of it (such as women of the child-bearing age). The PIS, on the other hand, may be characterized as a ‘pseudo-personalized’ document written to appear as being aimed at the individual participant (as seen in the use of the second-person pronoun in Examples (9) and (10) above). The phenomenon may possibly be seen as either a manifestation of, or a parallel to, Fairclough’s (2001) concept of synthetic personalization, i.e., the addressing of mass readerships as if they were individuals. The parallel should be acknowledged (if indeed it is a parallel), but it should be stressed that whereas Fairclough’s concept forms part of a critical agenda aimed at promotional discourse in particular, no criticism of the phenomenon (as manifested in the texts investigated in the present study) is intended here. Indeed, the personalization of documents aimed at mass audiences is recommended by plain-language style guides such as the one published by the US General Services Administration (2011). In the present case, the individualization of the document means that the special measures or precautions to be taken with various subcategories of participants are ‘translated’ into contingencies in the rewritten ‘target’ document, the PIS (*If you are ..., then ...*). Thus, in this particular case, the (more) personal/informal tenor (achieved through the direct address of the reader) is not only accompanied by, but actually results in, a higher level of de-contextualization and thus a slightly more ‘abstract’ text.

Apart from Generalization, Prediction and Conjecture, the only other RU category that occurs at a level of frequency that makes it deserving of comment is Action (4.5%). In many (though not all) cases, these RUs serve to direct the reader to consult with health care personnel for various reasons, as in:

(11) *Please speak with your doctor about other treatments for your disease.* (Eidos 2023b: 13)

4.3. The Dapagliflozin Viatris Summary of Product Characteristics

For the *Dapagliflozin Viatris* Summary of Product Characteristics (SmPC), the statistics are the following:

Table 4: Quantitative results for the *Dapagliflozin Viatris* SmPC.

Category	N	%
Generalization	151	24
Conjecture	0	0
Account	29	4.6
Prediction	3	0.5
Plan	0	0
Recount	397	63
Report	0	0
Observation	1	0.2
Reflection	0	0
Commentary	0	0
Action	49	7.8

The statistics reveal that the *SmPC* document is constructed around two RU types mainly, viz., Generalization and Recount, and to a much lesser extent Account and Action. Recount, which accounts for almost two thirds of the text, largely consists in RUs reporting the findings of the clinical trials preceding authorization of the drug for marketing, as in Example (12) below:

(12) *In one study in patients with type 2 diabetes mellitus with moderate renal impairment (GFR < 60 mL/min), a higher proportion of patients treated with dapagliflozin had adverse reactions of increase in creatinine, phosphorus, parathyroid hormone (PTH) and hypotension, compared with placebo.* (EMA 2023: 4)

As in Example (12), these RUs report (or ‘recount’, rather) the clinical trial results as past happenings or situations, in many cases accompanied by statistics, to provide an exact representation of the effects of the drug, including unwanted effects, the so-called *adverse reactions*. The curative mechanisms of the drug are also the subject of many Generalization RUs, albeit not as recounts of past happenings (as in Example 12) but as timeless representations, as in (13) below:

- (13) *The glucose lowering efficacy of dapagliflozin is dependent on renal function, and is reduced in patients with GFR < 45 mL/min and is likely absent in patients with severe renal impairment ...* (EMA 2023: 4)

Examples like (13) can be seen as the manifestation of scientific knowledge building: The three statements in (13) are clearly to be seen as inductions from a number of observations made in the clinical trials, whereby specific instances pave the way for abstraction into general, theoretical knowledge (concerning the effects of the active substance of the drug). As in (13), such cases of knowledge building tend to be grammatically realized in non-modulated, declarative clauses. In other cases, however, Generalization RUs in the SmPC – though still to be interpreted as messages with a timeless, generalized, content – are not merely representational in terms of pragmatic/rhetorical value but feature an ‘instructional’ or ‘directive’ element as well. This is the case when the effects of the drug (or limitations to the effect / unwanted side effects in relation to certain categories of patients) give rise to special precautions to be taken in connection with the *use* of the product. Thus, the sentence following the one in Example (13) reads:

- (14) *Therefore, if GFR falls below 45 mL/min, additional glucose lowering treatment should be considered in patients with type 2 diabetes mellitus ...* (EMA 2023: 4)

Grammatically, these ‘directive’ Generalization RUs typically feature a prominent interpersonal element in the form of modal deixis like *should* (see Halliday & Matthiessen 2014), as in Example (14) above. It is to be noted that, since the analytical framework applied here (the RU typology) largely disregards interpersonal semantics, or perhaps rather generalizes across the three metafunctions to arrive at the eleven degrees of concreteness/abstraction, what matters in terms of Example (14)’s positioning on the abstraction cline is the combination of the generalized CE *additional glucose lowering treatment* and the timelessness that in this case accompanies the interpersonal meaning of the *should*.

When it comes to the two remaining RU types represented in the SmPC, Account RUs mainly serve to point out limitations to the clinical trials conducted, or to the results emerging from the trials:

- (15) *There are no data from the use of dapagliflozin in pregnant women.* (EMA 2023: 7)

While the *are* of the EO must be interpreted as construing a ‘concurrent’ but timeless (‘habitual’) state of affairs, the CE *no data ...* is here interpreted as an ‘absent object’: the CE is not to be understood as a generalized entity but a concrete ‘portion’ of data (that does not exist).

Action RUs, for their part, mainly serve a meta- or intra-textual function, viz., in connection with cross-references inside the document, as in Example (16) below. The Action RU is the underlined bracketed string with the verb *see* in the imperative:

- (16) *Precipitating factors for DKA were as expected in a type 2 diabetes mellitus population (see section 4.4).* (EMA 2023: 12)

4.4. The Dapagliflozin Viatris PIL

Of the three lay-oriented texts investigated here, the *Dapagliflozin Viatris* PIL is the one that deviates the most from its ‘source’ in terms of RU composition and distribution. The statistics are:

Table 5: Quantitative results for the *Dapagliflozin Viatris* PIL.

Category	N	%
Generalization	86	36.6
Conjecture	32	13.6
Account	14	6.0
Prediction	12	5.1
Plan	2	0.9
Recount	5	2.1
Report	0	0
Observation	4	1.7
Reflection	29	12.3
Commentary	6	2.6
Action	45	19.1

The statistics reveal a rather ‘polarized’ distribution: The categories represented are the ‘top’ four and the three ‘bottom-most’ categories, whereas the four in the middle zone of the abstraction cline are virtually absent. Thus, there is some overlap with the distribution in the SmPC document regarding some of the ‘top-most’ categories (Generalization in particular, and to a lesser degree Account, figure in both texts), whereas the ‘lowest third’ of the cline occur considerably more prominently in the PIL, especially the Action category.

As in the SmPC, Generalizations are used in the PIL to characterize the drug (as a *type* or *brand* of medicinal product) in terms of its chemical composition (Example 17), its mechanism of action (Example 18) and its curative effect (Example 19), but also to explain and characterize the medical condition targeted by the drug (Example 20):

- (17) *Dapagliflozin Viatris contains the active substance dapagliflozin.* (EMA 2023: 59)
- (18) *Dapagliflozin Viatris works by removing excess sugar from your body.* (EMA 2023: 60)
- (19) *Dapagliflozin Viatris helps protect your heart from getting worse and improves your symptoms.* (EMA 2023: 60)
- (20) *In type 2 diabetes, your body does not make enough insulin or is not able to use the insulin it makes properly.* (EMA 2023: 60)

A marked difference between the PIL and SmPC document is that the former, unlike the latter, does not make use of the Recount category in ‘profiling’ the drug, the way the SmPC did by extensively reporting findings from the clinical trials. In the PIL, the ‘profiling’ of the drug only occurs in

Generalization RUs.

As for the use of Conjecture RUs, the PIL parallels the Information Sheet for prospective clinical-trial participants (see Subsection 4.2), in that Conjecture in both texts tends to be used in connection with contingency-dependent instructions for the patient:

- (21) [α] *Do not drive or use any tools or machines*, [β] *if you feel dizzy taking Dapagliflozin Viatris*. (EMA 2023: 62)

While the α -clause signifies instruction, or even a command/prohibition (congruently realized by an imperative combined with negative polarity (*Do not*)), the conditionality of the β -clause specifies the type of future circumstances under which only the instruction is relevant. As in the PIS document, the conditionality in these cases is here interpreted as the grammatical realization of a Conjecture, relating to the future use (imminent future use, that is) of the product.

Like Generalization RUs, Accounts typically also take part in setting out the characteristics of the product, but relate this ‘profiling’ of the drug to the patient and their situation:

- (22) (1) *They [= sodium glucose co-transporter-2 inhibitors] work by blocking the SGLT2 protein in your kidney*. (2) [β] *By blocking this protein*, [α] *blood sugar (glucose), salt (sodium) and water are removed from your body via the urine*. (EMA 2023: 59)

Whereas sentence (1) in Example (22) is a Generalization RU, sentence (2) belongs to the Account category. Possibly, sentence (2) originated as another Generalization that has been ‘translated’ into an Account RU (though this must remain speculation, of course): at least, with a slight grammatical modification, the semantic figure¹⁰ of the α -clause message (*salt and water are removed from the body via the urine*) represents a universal truth about a certain aspect of human physiology as such. In the two sentences in Example (22), on the other hand, the focus is narrowed to *your kidney* and *your body* specifically. Thus, while the EO *are* is still ‘timeless’, the CE *blood sugar (glucose), salt (sodium) and water* is now made to carry specific reference, representing the reader’s blood sugar etc. only, i.e., what must be considered an ‘absent object’.

In the ‘lower’ half¹¹ of the abstraction cline, only Reflection and Action are represented to any degree worth considering. Of these two, Reflection mostly occurs in subordinate clauses specifying circumstances under which precautions (such as refraining from taking the medicine or consulting with a healthcare professional) need to be taken by the patient, as in:

- (23) [β] *If you have diabetes*, [α] *it is important to stay on any diet and exercise program recommended by your doctor while taking Dapagliflozin Viatris*. (EMA 2023: 63)

The β -clause considers (or ‘reflects on’) the possibility of the patient having a certain medical condition (thus a ‘timeless’ state of affairs), viz., diabetes, which, if applicable, has certain consequences.

While Reflection occurs in moderate numbers (12.3%), Action is considerably more frequent (19.1%), coming in second after Generalization. The fact that these two categories (Generalization and Action) combined account for more than half the document shows the PIL genre to be largely a mixture of information (about the general characteristics of the product) and instruction. Around

¹⁰ Figure is here used in Halliday & Matthiessen’s (1999) sense, viz., as a configuration of Process and Participants (and Circumstances, possibly) at the semantic stratum.

¹¹ From the ‘upper’ half of the cline, the Prediction category will not be commented on here, owing to its very limited representation in the PIL.

half the occurrences of Action relate to communication, being ‘commands’ to contact a healthcare professional in case of problems, doubts relating to the medicine, unexpected side effects, etc. These ‘commands’/instructions are in all cases grammatically realized by imperatives:

(24) *Contact the doctor or the nearest hospital straight away ...* (EMA 2023: 60)

Most of the other instances of Action relate to how and when (and when not) to take the medicine:

(25) *Do not take Dapagliflozin Viatris if ...* (EMA 2023: 60)

(26) *Always take this medicine exactly as your doctor has told you.* (EMA 2023: 62)

(27) *Swallow the tablet whole ...* (EMA 2023: 62)

(28) *You can take your tablet with or without food.* (EMA 2023: 63)

In most of these cases also, the grammatical realization is the imperative. Only a few instances, like (28), are realized by modulated declaratives.

4.5. The Cochrane review and the plain language summary

Of the three pairs of texts investigated here, the *Cochrane review* and its plain-language summary is the one with the highest degree of qualitative correspondence between source and target, in terms of RU *types* represented (but with clear differences in terms of *quantitative* distribution, to be detailed below). Because of the qualitative correspondence, the analytical results for the two texts will be reported together in the present subsection. The statistics are the following:

Table 6: Quantitative results for the specialized *Cochrane review*.

Category	N	%
Generalization	253	15.4
Conjecture	6	0.4
Account	160	9.7
Prediction	37	2.2
Plan	3	0.2
Recount	1166	70.8
Report	6	0.4
Observation	6	0.4
Reflection	2	0.1
Commentary	9	0.6
Action	0	0

Table 7: Quantitative results for the Cochrane review plain-language summary.

Category	N	%
Generalization	32	48.5
Conjecture	0	0
Account	6	9
Prediction	1	1.5
Plan	0	0
Recount	24	36.4
Report	0	0
Observation	0	0
Reflection	3	4.5
Commentary	0	0
Action	0	0

The statistics show that both texts are primarily based on Generalization and Recount, and to a (much) lesser extent Account.¹² In both texts, all the other RU types occur to such a limited extent that no further consideration is warranted. As the statistics reflect, the predominant RU type in the specialized source text is Recount (70.8%), figuring prominently in the plain-language summary also, but with considerably lower frequency (30.8%). Example (29) below is from the source text and Example (30) from the target:

- (29) *Amongst symptomatic AF patients aged ≥ 65 years or < 65 years with ≥ 1 risk factors for stroke, the 'Catheter Ablation vs Anti-arrhythmic Drug Therapy for Atrial Fibrillation Trial (CABANA)' showed a reduction in all-cause mortality and cardiovascular hospitalisation for those randomised to catheter ablation (51.7% versus 58.1%; HR 0.83, 95% CI 0.74-0.93, $P = 0.001$) (Packer 2019). (Kukendrarajah et al. 2024)*
- (30) *Heart failure was observed in some patients treated with propafenone, flecainide, sotalol, amiodarone, vernakalant, and placebo, ... (Kukendrarajah et al. 2024)*

In both texts, Recount is used to represent results from past clinical trials reported in the clinical literature, as in the examples above. In the plain-language summary, moreover, Recount is used to report (or 'recount') the procedures undertaken by the authors of the source text in conducting the review, e.g., (Example 31, from the *summary*): *We compared and summarised the results of the*

¹² Only Generalization and Recount RUs in the two texts will be commented on.

studies ... (Kukendrarajah et al. 2024).

As in the *Summary of Product Characteristics* (see Subsection 4.3), Generalizations in both texts reflect scientific knowledge building ‘in action’, representing the generalized, theoretical conclusions emerging from the experimental findings:

(32) (from the specialized *review*): *Pharmacological cardioversion seems to be an effective option for paroxysmal AF, but onset of action of the most effective options may vary from 30 to 90 minutes (e.g. vernakalant, flecainide, antazoline, and ibutilide) to longer; ...* (Kukendrarajah et al. 2024).

(33) (from the *summary*): *While electrical cardioversion is highly effective in dealing with all arrhythmias, the efficacy of drugs varies, ...* (Kukendrarajah et al. 2024)

Strikingly, since the plain-language summary is mainly focused on the ‘central lessons’ to be derived from the *review*, and to a considerably lesser extent focused on the specific results of individual trials, the proportion of Generalizations in the *summary* (48.5%) is much higher than in the *review* (15.4%). Thus, perhaps counterintuitively, this focus of the *summary* contributes to a considerably more abstract text than its specialized source.

Conclusion

As previously mentioned, the investigation proceeded from the assumption that the rewriting of expert-oriented texts into lay-oriented ones would correlate with a ‘movement’ away from generalized/abstract meanings towards a higher degree of ‘concreteness’ and particularity. However, the analyses showed considerably greater nuance, revealing this expectation to be unfounded. Thus, the overall conclusion is that, judging from this qualitative study, lay-oriented summarized genres are not necessarily more ‘concrete’ in semantics than their specialized counterparts. Rather, the in- or decrease in abstraction (as compared to the specialized source) appears to depend on the overall purpose (i.e., the genre) of the target text and its specific tenor. For the three text pairs, the ‘movement’ in level of abstraction can be summarized as follows: While the genre of Patient Information Leaflets did indeed reflect a higher degree of concreteness than its specialized source, particularly owing to a stronger instructional tenor, with advice/instruction aimed directly at the reader, the information sheet for clinical trial participants (the PIS) exhibited very limited change, with much the same level of abstraction maintained in source and target, despite the target text being addressed directly to the lay reader with information about ‘what to expect’. The comparable level of abstraction may be explained by relatively similar generic purposes, in that both genres (the protocol and the PIS) are future-oriented ones outlining planned happenings and interventions. In the third genre pair (the *Cochrane review* and the lay summary), the semantic shifts even turned out to be counterintuitive, with the ‘target’ text featuring a proportionately higher number of abstract meanings than its source. As in the case of the scientific protocol-PIS pair, the generic purpose of the *review* and its summary are relatively similar, but the higher level of abstraction in the summary is explained by its specific purpose, which was to provide only the key insights from the review. These were expressed by means of Generalization RUs, largely ignoring the source text’s account (or Recounts) of specific findings in the individual studies reviewed.

In rounding off, one point of similarity between the three case studies in terms of research design may be further commented on, which is that all three involved one source text only. What was thus excluded from the investigation were cases where a lay-oriented target text is derived from more than one source text. This is the case with the medical lay-oriented genre named *medicine overview*, also featured on the website of the EMA. Texts belonging to this genre set out the central

characteristics of a given medicinal product and summarize the results of the clinical trials which enabled the drug to be authorized by the EMA for marketing in the EU. Like the target texts investigated here, the *medicine overview* is a product of rewriting, but with two different (specialized) sources, namely the *Summary of Product Characteristics* (see Section 3 above) and the *Public Assessment Report*, whose most important part is a detailed account of the results of the clinical trials preceding authorization. An investigation of potential source-to-target shifts in concreteness/abstraction in a case of dual-source genre transformation like this will be an obvious next step in the specific area of LSP linguistics and knowledge communication research that focuses on rewritten lay-oriented genres.

References

Primary sources:

- Eidos (2023a). *An Open-Label Extension and Safety Monitoring Study of Acoramidis (AG10) in Participants with Symptomatic Transthyretin Amyloid Cardiomyopathy Who Completed the Phase 3 ATTRIBUTE-CM Trial (AG10-301)*. <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2024-515092-36-00>. Accessed 17-07-2025.
- Eidos (2023b). *An Open-Label Extension and Safety Monitoring Study of Acoramidis (AG10) in Participants with Symptomatic Transthyretin Amyloid Cardiomyopathy Who Completed the Phase 3 ATTRIBUTE-CM Trial (AG10-301) – Main Participant Information Sheet*. <https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2024-515092-36-00>. Accessed 17-07-2025.
- European Medicines Agency (EMA) (2023). *Dapagliflozin Viatris : EPAR – product information*. https://www.ema.europa.eu/en/documents/product-information/dapagliflozin-viatris-epar-product-information_en.pdf. Accessed 17-07-2025.
- Kukendrarajah, Kishore, M. Ahmad, M. Carrington, A. Ioannou, J. Taylor, Y. Razvi, N. Papageorgiou, GE Mead, IF Nevis, F. D'Ascenzo, SB Wilton, PD Lambiase, CA Morillo, JSW Kwong & R. Providencia (2024). 'External electrical and pharmacological cardioversion for atrial fibrillation, atrial flutter or atrial tachycardias: a network meta-analysis'. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013255.pub2/full>. Accessed 17-07-2025.

Secondary sources:

- Carman, Kristin L., Pam Dardess, Maureen Maurer, Shoshanna Sofaer, Karen Adams, Christine Bechtel & Jennifer Sweeney (2013). 'Patient and family engagement: A framework for understanding the elements and developing interventions and policies'. *Health Affairs* 32(2): 223–231. <https://doi.org/10.1377/hlthaff.2012.1133>.
- Cloran, Carmel (2010). 'Rhetorical unit analysis and Bakhtin's chronotope'. *Functions of Language*, 17(1): 29–70. <https://doi.org/10.1075/fol.17.1.02clo>.
- Coulter, Angela & Jo Ellins (2007). 'Effectiveness of strategies for informing, educating, and involving patients'. *BMJ* 335(7609): 24–27. <https://doi.org/10.1136/bmj.39246.581169.80>.
- Directorate-General for Health and Food Safety (2021). *Good lay summary practice*. https://health.ec.europa.eu/document/download/8a42b8f5-4ec3-4667-969c-3dd89ea8b270_en?filename=glsp_en.pdf. Accessed 08-05-2025.
- Eggs, Suzanne (2004). *An Introduction to Systemic Functional Linguistics*. London: Continuum.
- Epstein, Ronald M., & Richard L. Street Jr. (2008). *Patient-centered care for the 21st century: Physicians' roles, health systems and patients' preferences*. Philadelphia: ABIM Foundation.
- Fairclough, Norman (2001). *Language and Power* (2nd ed.). Harlow, Eng.: Longman.

- Halliday, Michael A. K. (1973). *Explorations in the Functions of Language*. London: Edward Arnold.
- Halliday, Michael A. K. (1978). *Language as Social Semiotic: The Social Interpretation of Language and Meaning*. London: Edward Arnold.
- Halliday, Michael A. K. & Christian M. I. M. Matthiessen (1999). *Construing Experience through Meaning: A Language-based Approach to Cognition*. London: Cassell.
- Halliday, Michael A. K. & Christian M. I. M. Matthiessen (2014). *Halliday's introduction to functional grammar*. London: Routledge.
- Halliday, Michael A. K. & Ruqaiya Hasan. (1976). *Cohesion in English*. London: Longman.
- Halliday, Michael A. K. & Ruqaiya Hasan. (1989). *Language, Context, and Text: Aspects of Language in a Social-Semiotic Perspective* (2nd ed.). Oxford: Oxford University Press.
- Hasan, Ruqaiya (1995). 'The conception of context in text'. In Fries, Peter H. & Michael Gregory (eds.), *Discourse in Society: Systemic Functional Perspectives*. Norwood, New Jersey: Ablex Publishing Corporation. 183–284.
- Hasan, Ruqaiya (1999). 'Speaking with reference to context'. In Ghadessy, Mohsen (ed.), *Text and Context in Functional Linguistics*. Philadelphia: John Benjamins. 219–328.
- Hasan, Ruqaiya (2014). 'Towards a paradigmatic description of context: Systems, metafunctions, and semantics'. *Functional Linguistics* 1(9): 1–54.
<https://doi.org/10.1186/s40554-014-0009-y>.
- Hasan, Ruqaiya, Carmel Cloran, Geoffrey Williams & Annabelle Lukin (2007). 'Semantic networks: The description of linguistic meaning in SFL'. In Hasan, Ruqaiya, Christian M. I. M. Matthiessen & Jonathan Webster (eds.), *Continuing Discourse on Language: A Functional Perspective*. London/Oakville: Equinox. 697–738.
- Hill-Madsen, Aage (2015a). 'Lexical Strategies in Intralingual Translation between Registers'. *HERMES – Journal of Language and Communication in Business*, 27(54): 85–105.
<https://doi.org/10.7146/hjlc.v27i54.22949>.
- Hill-Madsen, Aage (2015b). 'The 'Unpacking' of Grammatical Metaphor as an Intralingual Translation Strategy: From De-Metaphorization to Clausal Paraphrase'. In Maksymski, Karin, Silke Gutermuth & Silvia Hansen-Schirra (eds.), *Translation and Comprehensibility*. Berlin: Frank & Timme. 195–226.
- Hill-Madsen, Aage (2022a). 'Semantic Density and Gravity in Lay-Oriented Medical Knowledge Communication: The Case of the EPAR Summary for the Public'. *Nordic Journal of English Studies*, 21(2): 195–225. <https://doi.org/10.35360/njes.781>.
- Hill-Madsen, Aage (2022b). 'Transformational Strategies in Diaphasic Translation: Three Case Studies'. *Perspectives – Studies in Translation Theory and Practice*, 30(4): 643–661.
<https://doi.org/10.1080/0907676X.2021.1953085>.
- Hill-Madsen, Aage (2025). 'Semantic Density and Gravity in Lay-Oriented Medical Knowledge Communication II: The Case of Patient Information Leaflets'. *Nordic Journal of English Studies*, 24(1): 41–74. <https://doi.org/10.35360/njes.v24i1.41116>.
- Hill-Madsen, Aage & Morten Pilegaard (2019). 'Variable Scope for Popularization of Specialized Terminology: The Case of Medico-Pharmaceutical Terms'. *Fachsprache – Journal of Professional and Scientific Communication*, 41(1-2): 22–40.
<https://doi.org/10.24989/fs.v41i1-2.1623>.
- Kastberg, Peter (2011). 'Knowledge asymmetries – Beyond "to have and have not"'. *Fachsprache – Journal of Professional and Scientific Communication*, 33(3-4): 137–151.
<https://doi.org/10.24989/fs.v33i3-4.1369>.
- Martin, James R. (1992). *English Text: System and Structure*. Amsterdam/Philadelphia: John Benjamins.
- Martin, James R. & David Rose (2008). *Genre Relations: Mapping Culture*. London: Equinox.

- Patton, Michael Quinn (2002). *Qualitative Research & Evaluation Methods* (3rd ed.). Thousand Oaks/London: SAGE.
- Maton, Karl (2013). 'Making semantic waves: A key to cumulative knowledge-building'. *Linguistics and Education*, 24(1): 8–22. <http://dx.doi.org/10.1016/j.linged.2012.11.005>.
- Maton, Karl (2014). *Knowledge and Knowers: Towards a Realist Sociology of Knowledge*. London/New York: Routledge.
- Maton, Karl & Yaegan J. Doran (2017). 'Semantic density: A translation device for revealing complexity of knowledge practices in discourse, Part 1 – clausing and sequencing'. *Onomázein – Journal of Linguistics, Philology and Translation*, Special issue II: 77–10. <https://doi.org/10.7764/onomazein.ne2.04>.
- Pilnick, Alison (1998). '“Why didn't you say just that?” Dealing with issues of asymmetry, knowledge and competence in the pharmacist/client encounter'. *Sociology of Health and Illness*, 20(1): 29–51. <https://doi.org/10.1111/1467-9566.00079>.
- US General Services Administration (2011). *Federal Plain Language Guidelines*. <https://www.plainlanguage.gov/media/FederalPLGuidelines.pdf>. Accessed 16-07-2025.

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- 17.0 What will happen to the Results of this Study?

- 18.0 Who has Reviewed this Study?
- 19.0 Who to Contact with Questions or Report a Possible Study Related Injury or Reaction

Appendix C: List of contents for the *Dapagliflozin Viatris SmPC*

1. NAME OF THE MEDICINAL PRODUCT
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
3. PHARMACEUTICAL FORM
4. CLINICAL PARTICULARS
 - 4.1 Therapeutic indications
 - 4.2 Posology [= *dosage*] and method of administration
 - 4.3 Contraindications [= *factors/conditions that make the treatment inadvisable*]
 - 4.4 Special warnings and precautions for use
 - 4.5 Interaction with other medicinal products and other forms of interaction
 - 4.6 Fertility, pregnancy and lactation
 - 4.7 Effects on ability to drive and use machines
 - 4.8 Undesirable effects [= *side effects*]
 - 4.9 Overdose
5. PHARMACOLOGICAL PROPERTIES
 - 5.1 Pharmacodynamic properties [= *the effects and modes of action of the drug upon the body*]
 - 5.2 Pharmacokinetic properties [= *the rate at which drugs are absorbed, distributed, metabolized and eliminated by the body*]
 - 5.3 Preclinical safety data
6. PHARMACEUTICAL PARTICULARS
 - 6.1 List of excipients [= *ingredients added to a drug for purposes other than the therapeutic or diagnostic effect*]
 - 6.2 Incompatibilities
 - 6.3 Shelf life
 - 6.4 Special precautions for storage
 - 6.5 Nature and contents of container
 - 6.6 Special precautions for disposal
7. MARKETING AUTHORISATION HOLDER
8. MARKETING AUTHORISATION NUMBER(S)
9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
10. DATE OF REVISION OF THE TEXT

Appendix D: List of contents for the *Dapagliflozin Viatris PIL*

1. What Dapagliflozin Viatris is and what it is used for
2. What you need to know before you take Dapagliflozin Viatris
3. How to take Dapagliflozin Viatris
4. Possible side effects
5. How to store Dapagliflozin Viatris
6. Contents of the pack and other information

Appendix E: List of contents for the *Cochrane* review

Abstract

PICOs (*Population, Interventions, Comparison, Outcome*)

Plain Language Summary

Authors' conclusions

Background

Objectives

Methods

Results

Discussion

Figures and tables

References