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CONSENT METHODS FOR THE ENROLMENT IN ACUTE CLINICAL TRIALS: A FUNCTIONAL LINGUISTIC PERSPECTIVE ON AN ABRIDGED INFORMATION SHEET

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Abstract: This article presents a functional linguistic analysis of a brief patient information sheet and consent form used in an international stroke study. The readability of the text document was assessed based on the fog index which fails to adequately capture the complexity of the standardised institutional text and the patients' comprehension processes. Using a multi-level linguistic framework ((i) word, (ii) phrase/sentence, and (iii) text level), the analysis reveals various linguistic phenomena — including complex syntax, linguistic action patterns, parentheses, and technical terminology — that may challenge patients' understanding, particularly in stressful and emotional situations in which they might also suffer from (temporal) cognitive impairments due to the acute stroke. The article argues that qualitative, hermeneutic, and (functional) linguistic approaches need to be used to assess and improve the readability of text documents with ethical and legal functions in the context of clinical trials. Based on the linguistic analysis, a revised version of the information sheet is proposed to enhance comprehension. Only when patients understand the provided information, they can give their informed consent which is a (research) ethical standard.

Keywords: text analysis; functional linguistics; readability; comprehension; fog index; consent form.

1. Introduction

An international stroke study used a text document (i) to inform stroke patients about (a) their condition and (b) the study and (ii) to seek their consent to being enrolled in the study. To measure the readability of this text the so-called fog index was used. This readability measure is insufficient for modelling and operationalising readability.

In this article a functional linguistic analysis of the text document is carried out to identify potential comprehension difficulties. On this basis a modification of the text document is suggested.

Law *et al.* (2022: 1141) point out that "interventions are time sensitive" when it comes to cases of acute stroke. Hence, it is crucial in such contexts to get consent as quickly as possible for the enrolment of patients in a clinical trial study. In the discussed study there is a distinction between a 1-stage and a 2-stage consent, i.e. a "full written consent" (*ibid.*) (1-stage consent) and an "initial brief consent followed by full consent" (*ibid.*) afterwards (2-stage consent). The consent was either provided (i) by the patients themselves or (ii) by a relative or (iii) by a physician. In this article, we deal with the abridged consent document. This 2-stage consent (initial brief consent followed by full written consent later) led to "shorter times to enrolment, while maintaining good participant retention" (*ibid.*).

Specific standardised templates were used for the creation of the information sheet and consent forms:

> The information sheets and consent forms were designed according to the principles outlined in the Medicines for Human Use (Clinical Trials Regulations) 2004 and European Clinical Trials Directive (EC2001/20) and based on templates provided by the UK Health Research Authority. (Law *et al.* 2022: 1142)

Of course, these consent seeking measures "were approved by each participating country or center's ethics review committee" (*ibid.*). From an ethical perspective it is essential to get an informed consent of potential participants (e.g. Riemer 2014; Flick 2012). It needs to be reflected on what can count as an informed consent if participants do not really understand the conditions and processes of the study researchers want them to enrol in.

As mentioned, this article focusses on the brief information sheet. It "consisted of only one page of information […] that explained the condition (ICH), treatment (tranexamic acid or placebo), blinding, and that there would be an additional computed tomography (CT) scan after 24 hours" (Law *et al.* 2022: 1143). The short consent form needs to be signed only once by patients which additionally makes the process faster (*ibid.*).

The short consent forms for patients are almost identical to the short consent forms for legal representatives, i.e. patients' relatives. In this article, we will focus on the short consent form for patients and analyse how its readability is modelled.

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The readability of the consent form was calculated by use of the fog index, "which assesses readability and estimates the level of education needed to understand the text on the first reading" (*ibid.*). According to the analysis of Law *et al.* the fox index of the short consent form for patients is 7.8 (*ibid.*). This means that the text can be understood by "a 13- or 14-year-old […] at first reading" (*ibid.*). In this context, the question needs to be raised whether this is an appropriate conceptualisation of readability.

According to the authors, the 2-stage consent procedure was quite successful. In total, 2.325 patients from 12 different countries were recruited for the clinical trial (*ibid.*: 1144). For 86.4 per cent of the enrolled patients through a form of 2-stage consent (patient, relative, medical doctor) full consent was given afterwards. Law *et al.* are convinced that the short information and consent form provided patients sufficient information for their decision-making (*ibid.*: 1145). The authors assume that the shorter text has a "better readability" (*ibid.*).* Consequently, it "reduced reading time and enabled easier understanding" (*ibid.*). We want to methodologically and linguistically challenge this claim, as there is no data available on the individual understanding processes of patients that participated in the clinical trial. Also, the authors themselves discuss some shortcomings of the study:

> One limitation of this study is that we have not surveyed patients, relatives, or doctors regarding the consent process. Future trials could explore the implications of 2-stage consent on participants' experience, including if they felt that they were appropriately involved, the quality of interaction with researchers, what they felt was important at the time of decision-making, their perception, understanding of their contribution to research as study participants, recall of the consent process at a later date, and postenrollment discussion. (Law *et al.* 2022: 1147)

To our understanding it is vital to collect data of the patients who are involved in such studies. Especially when research is conducted with real persons who are social beings, it is crucial to regard and treat them as involved informants whose views and experiences are valued and considered. You cannot conclude from a mathematical formula whether a person has understood a text or not, especially not when this formula reduces the linguistic complexity of text comprehension to an operationalizable minimum. As the phrase *mathematical formula* in reference to the fog index already implies, the concepts TEXT and UNDERSTANDING (or TEXT COMPREHENSION) are captured in a quantitative way. A text is more than a numeric total of words and sentences. Approaches such as the fog index don't do justice to the complexity of text and comprehension. Qualitative (explorative-interpretative) and hermeneutic approaches are necessary to scientifically understand whether patients really do sufficiently understand the information conveyed in such brief consent forms and whether they can give an informed consent on such a basis. If the models that assess the readability of a critical text document which is used for getting an informed consent of patients to enrol them in a clinical trial are too simple, what exactly is measured then? We believe that the validity of important constructs is reduced in such cases. If quality criteria

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are not met, the value of the whole study is at risk. Furthermore, in this specific context ethical standards need to be addressed and questioned.

This is the text of the brief information sheet for patients:

(1) Brief Patient Information Sheet
(2) Title of Study: Tranexamic acid for Haemorrhage Stroke (TICH2)
(3) “You have had a haemorrhagic stroke (a stroke caused by bleeding in the brain) that needs urgent care.
(4) You will get all the usual emergency care for stroke that we provide at this hospital.
(5) As well as this, we would like to include you in an international study.
(6) This study will see whether a drug called tranexamic acid reduces bleeding inside the head after haemorrhagic stroke.
(7) We hope that the drug will lead to a better recovery.
(8) We know that the drug reduces bleeding in other types of haemorrhage conditions, without side effects, and the sooner the drug is given the more effective it is.
(9) As yet we don’t know if it works in haemorrhagic stroke.
(10) As part of the study, you will receive an injection into a vein followed by a drip over eight hours.
(11) Half the patients in the study will get the tranexamic acid and half a dummy drug (a liquid which does not contain tranexamic acid).
(12) We won’t know until the end of the study who received which treatment.
(13) We will need to collect some information about your medical condition and send it to a central office in Nottingham.
(14) We would also like to perform one additional CT brain scan (similar to the one you had to diagnose your stroke) to monitor the effect of the treatment.
(15) If you would like to know more about our study now, then we will tell you.
(16) But otherwise we will tell you more about it later.
(17) Are you happy for us to go ahead with the study treatment?"
(18) Yes, I am happy for you to go ahead.
(19) Name:
(20) Signature:
(21) Date:
(22) Witness name and signature:
(23) Witness Name:
(24) Witness Signature:
(25) Date:
(26) (Complete only where required)[1]

[1] We want to thank Nicola Sprigg and Vasileios Tentolouris-Piperas who were both involved in the study for providing the text document.

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The text can be found in a document which contains supplemental materials and supplemental methods. The final version (final version 1.0) of the brief patient information sheet (*Supplemental Methods V*) is dated November 19, 2012. Basically, it is a template that needs to be printed on the medical institution's corporate paper. We numbered each unit for reference reasons. Unit (1) is the headline of the form. Unit (2) is the title of the study. The main text starts at unit (3) and ends at unit (17). This is also marked by inverted commas. From unit (3) to unit (17) a unit corresponds to a sentence. In unit (18) the perspective is changed. Now it is no longer the researchers who inform the patient and seek her/his (informed) consent, but the patient herself/himself who can give consent which is the purpose of this specific institutional document. This shift is marked using *I*. In classic grammatical terminology *I* is a personal pronoun. We follow the concept of Bühler (1999[1934]) that *I* is a personal deictic expression which locates the deictic centre at the speaker. However, from unit (19) to unit (26) we clearly see the character of the document. It is a consent form. Hence, it is a standardised text that is of legal relevance. Here the patient is no longer just a recipient. Instead, she/he needs to become active, i.e. she/he needs to write down her/his name, the date, and sign the form. Such forms serve the purpose of the institution and need to comply with the current legal framework. These texts are standardised due to legal reasons and due to reasons related to the need of processing clients of the institution in an economic way which is specific for the institution.

2. Linguistic analysis

In the following, we present a functional linguistic analysis of the brief patient information sheet. Our approach is like the linguistic analysis of a textbook text for students with German as a Second Language (GSL) by Sotkov and Frank (2021). We use three analytical layers: (i) word level, (ii) phrase and sentence level, and (iii) text level. This holistic functional linguistic approach can be used for the analysis of texts from various institutions. However, it is important to point out though that research on language comprehension needs to systematically and empirically consider the comprehension processes of real listeners and readers (Sotkov 2023).

Table 1 gives an overview of the subcategories of the three different levels of text analysis which are – of course – intertwined and merely presented separately for analytical reasons.

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Table 1. Text analysis levels and their subcategories.

Levels of linguistic analysis		
word level	**phrase/sentence level**	**text level**
• compounds • (personal) deictic expressions • metaphors, metonymies, idioms – figurative language • (inflectional) morphology • prepositions • quantifiers • technical terms	• syntax: analepses/ellipses, complex phrases, subordinate (and relative) clauses, parentheses, yes-no questions • technical language use	• (thematic) coherence: introduction, continuation and development of a topic • linguistic action patterns • perception conditions • text connectivity (means of text structuring) • text continuity (reader-text interaction), text deixis, and text type

2.1. Word level

First, we deal with the word level. The subcategories (i) compounds, (ii) deictic expressions, (iii) figurative language, (iv) morphology, (v) prepositions, (vi) quantifiers, and (vii) technical terms will be discussed here.

2.1.1. Compounds

The text contains eleven compounds (the head of each compound is underlined): (i) *patient information sheet* (text unit (1))[2], (ii) *tranexamic acid* ((2), (6), (11)), (iii) *haemorrhage stroke* ((2), (3), (6), (9)), (iv) *emergency care* ((4)), (v) *haemorrhage conditions* ((8)), (vi) *side effects* ((8)), (vii) *dummy drug* ((11)), (viii) *CT brain scan* ((14)), (ix) *study treatment* ((17)), (x) *witness name* ((22), (23)), (xi) *witness signature* ((22), (24)). All these compounds are nouns. They all consist of one head and one or – in two cases – two modifiers which restrict the meaning of the head, e.g. $patient_{\text{modifier1}}$ $information_{\text{modifier2}}$ $sheet_{\text{head}}$. This type of compound is an endocentric compound. From a set-theoretical perspective they introduce a specific relation: the sum of sheets is greater than the sum of information sheets, the sum of information sheets is greater than the sum of patient information sheets (Thielmann 2021: 52). The term *acid* is a chemical term. It is polysemous. In the context of the patient information sheet the term *acid* refers to a (medical) drug. However, *acid* is the superordinate term, *tranexamic acid* is more specific and therefore the subordinate term. The term *emergency care* (subordinate term) is more specific than *care* (superordinate term). *Haemorrhage conditions*

[2] From here on the text unit number(s) will be provided in parentheses without using the expression *text unit* (or *text units*) in front.

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(subordinate term) is a specification of *conditions* (superordinate term). *Drug* is the superordinate term, whereas *dummy drug* is the subordinate term. For the compound *CT brain scan*, *scan* is the broadest term (superordinate level). *Brain scan* (basic level term) is more specific than *scan* and *CT brain scan* (subordinate level) is even more specific than *brain scan*. The same holds true for *sheet* (superordinate level term), *information sheet* (basic level term) and *patient information sheet* (subordinate level term). This also applies to *stroke* (superordinate term) and *haemorrhage stroke* (subordinate term), as well as to *treatment* (polysemous, superordinate term) and *study treatment* (subordinate, more specific term). The specification *study treatment* is important, as there is a difference between a normal treatment of strokes and an additional treatment once enrolled in the study. Of course, this relation also holds true for *effects* and *side effects*, *name* and *witness name*, and *signature* and *witness signature*. In terms of comprehension compounds and the relations they convey might add a layer of complexity to the reader's understanding of the text document.

2.1.2. (Personal) deictic expressions

There are three personal deictic expressions in the text: (i) *we*, (ii) *you*, and (iii) *I*. The term *we* ((4), (5), (7), (8), (9), (10), (12), (13), (14), (15), (16)) expresses (a collective) in-group membership and closeness. The word *you* ((3), (4), (5), (10), (13), (14), (15), (16), (17), (18)) refers to an out-group entity. *I* ((18)) is a personal deictic expression which refers to a close single entity. It is remarkable that the reader as a potential study subject is addressed with the term *you* throughout the short consent document. Only in (18) the perspective changes to the (insider) view of the patient which is expressed by the term *I*. This is relevant for the institutional purpose of the text document – getting the consent of the patient. The collective term *we* refers to the medical researchers who oversee this study. The patient and potential study subject is not part of this group.

2.1.3. Metaphors, metonymies, idioms – figurative language

To embrace the linguistic complexity on the word level, it should be included whether the text contains metaphors, metonymies, or idioms. Especially new metaphors can be difficult to understand (Sotkov 2023). The (polysemous) lexical verb *work* ((9): *[…] we don't know if it works in haemorrhagic stroke*) can be identified as a highly lexicalised metaphor. Due to its degree of lexicalisation and its high frequency it won't be recognised as a metaphor by linguistic laymen. The term *drip* ((10)) is a metonymy (*pars pro toto*). The compound noun *dummy drug* ((11)) which is used instead of the term *placebo* contains the modifier *dummy* which is polysemous and derived from the Old English adjective *dumb*. It can also be classified as a lexicalised metaphor. For readers with English as their first language (L1) these expressions should not cause any comprehension difficulties under normal circumstances. For patients who have just suffered a stroke we have to assume a special situation and a potential (temporal) impairment of their

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linguistic capabilities which might include reading (and metaphor) comprehension.

2.1.4. (Inflectional) Morphology

In this subcategory we differentiate between (i) verb morphology, (ii) noun morphology, and (iii) adjective morphology. We will mainly limit our analysis to the formation of word forms that encode grammatical information, i.e. inflectional morphology.

In the text document the following verb categories are grammatically coded: (a) aspect, (b) person, (c) tense, (b) voice. In (3) (*You have had a haemorrhagic stroke (a stroke caused by bleeding in the brain) that needs urgent care*) the present perfect is used. The perfect aspect of the verb expresses that an event occurred in the past (here: the stroke) and that the result of this event is relevant for the present situation, i.e. the time of reference (e.g.: *Your stroke needs urgent care [now]*). In English the present perfect combines the present tense with the perfect aspect. Hence, it is often labelled *present perfect tense*.[3] The form consists of the auxiliary verb *have* (here: 2nd person singular) and the past participle form of the lexical verb (here: *had* (past participle of *have*)). The text features four tenses: (i) present perfect tense (as discussed above), (ii) present tense, (iii) past tense, and (iv) *will*-future. *Will*-future is used in (4), (6), (7), (10), (11), (12), (13), (15), and (16) (nine times in total). It is formed by using the auxiliary verb *will* in combination with the infinitive form of the lexical verb, e.g. *You will get all the usual emergency care for stroke […]* ((4)). In (12) the negation is used (*We won't know […]*) which is formed by using the auxiliary verb *will*, the negation particle *not*, and the infinitive form of the lexical verb (here the contracted form *won't* is used). The past tense is used twice in the text. In (12) one can find the regular past tense form of the verb *receive* which is built by adding –(*e*)*d* to the stem (*receive-d*). A complex scenario is expressed using the *will*-future and the past tense in this sentence: *We won't know*$_{\textit{will}\text{-future and negation}}$ *until the end of the study who received*$_{\text{past tense}}$ *which treatment.* The *will*-future projects into the future. A scenario needs be mentally constructed in the sense that the *will*-future shifts the time of reference (the *now*-situation (the speaker's deictic centre)) to the future in which the study is already finished. From this perspective the past tense (*received*) can be explained. As at a specific point of time in the future the study will be over, the process step of giving patients the drug is an action that is mentally conceptualised as being in the past due to the shift of the time of reference to the future induced by the *will*-future. The past tense use in (14) is more straightforward to explain. The present tense is used in the main clause. Hence, there is no mental shift of the *now*-situation to a different time of reference. The past tense (*had*) simply refers to an event that lies in the past from the present perspective. The present perfect tense is used only once in the text ((3)). In the majority of sentences the present tense is used ((3), (4), (5), (6), (7), (8), (9), (11), (14), (15), (17), (18) (12 times in total)). In (9) the negation of the present

[3] We cannot discuss here whether the English present perfect is really a tense or not.

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tense verb is used which is formed by the auxiliary verb *do*, the negation particle *not* (here: contracted form *don't*), and the infinitive form of the lexical verb (*know*). This is also the case in (11) (*a liquid which* *does*$_{\text{3rd person singular, auxiliary verb}}$ *not*$_{\text{negation particle}}$ *contain*$_{\text{lexical verb}}$ *tranexamic acid*). Although the present tense is the most frequently used tense in the text, it is obvious that other tenses are used as well (especially *will*-future). This adds a certain layer of complexity to the text and potentially makes it more difficult for patients to understand everything correctly which is the basis of an informed consent.

So far, we have pointed out that different tenses are used, negations occur, and the perfect aspect is used. In addition to that the grammatical information for person is coded in the verb. This is relevant for the present perfect and the present tense. The 1st person singular present tense form is used in (18). The 2nd person present perfect or present tense form is used in (3), (15), and (17). The 3rd person singular form of the present tense verb is used in (3), (6), (8), (9), and (11). Finally, the 1st person plural form of the present tense is used in (4), (5), (7), (8), and (9).

Another grammatical information which is transported by the verb form is voice. The active voice is used in almost all verb instances. The passive voice is only used in (3), (8), and (10). A prototypical use of the passive voice can be found in (8) (*the sooner the drug is given […]*). The passive voice requires an auxiliary verb (here: 3rd person singular, present tense of *be* (*is*)) and the past participle of the lexical verb (here: *give* (*given*)). By using the passive voice, the thematic role AGENT (*we*, i.e. the researchers, medical stuff) is backgrounded, whereas the main information relevant for the study treatment is foregrounded (x_{AGENT} *gives* z_{THEME} *to* $y_{\text{RECIPIENT}}$ vs. z_{THEME} *is given* (*to* $y_{\text{RECIPIENT}}$ (*by* x_{AGENT}))). Used in the active voice, the verb *give* is ditransitive (x_{subject} gives $y_{\text{indirect object}}$ $z_{\text{direct object}}$). We argue that in (3) as well as in (10) there are two other passive voice instances: (i) *a stroke [which is] caused by bleeding in the brain* (3), (ii) *an injection into a vein [which is] followed by a drip […]* (10). Here, an ellipsis (Hoffmann 1998) is used.[4] The infinite verb form (past participle (*caused*, *followed*) is realised, whereas the finite verb form (3rd person singular, present tense form of the auxiliary verb *be* (*is*)) as well as the relative pronoun *which* are left out. These elements can be left out because of the reader's linguistic knowledge. The passive voice is commonly used in language for special purposes contexts.

It needs to be mentioned that there are several sentences in the text which include an infinitive verb form ((5), (13), (14), (15), (17), (18)). Also, the gerund is used in the text ((3), (6), (8)). By adding the suffix *-ing* to the verb stem (here: *bleed* + *-ing*) the verb chances its category to a noun. These processes belong to the category of derivation, i.e. derivational morphology. The gerund is used in prepositional phrases (PP) (*a stroke caused by bleeding in the brain* (3)) and can function as a subject or object ([…] *tranexamic acid reduces* bleeding$_{\text{direct object}}$ *inside the head […]* (6), […] *the drug reduces* *bleeding*$_{\text{direct object}}$ *in other types of haemorrhage conditions […]* (8)).

[4] Hoffmann distinguishes between *ellipsis* and *analepsis*. Whereas an analepsis is based on priorly verbalised knowledge in a text or talk and is a form of continuation, an ellipsis has a different source (linguistic and situational knowledge, etc.) (Hoffmann 1998).

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Remarkably, (1), (2), and (19) to (25) have no (finite) verb, i.e. these units aren't sentences. (1) and (2) are headlines and structural elements of the text. It is typical that headlines don't have finite verb forms. Units (19) to (25)[5] are – as mentioned above – typical for institutional forms, i.e. text documents that require stripped-down language for the elicitation of personal and legal data which is necessary for the routinised processing of the institutional clients (here: the patients and potential study subjects).

When it comes to the inflectional morphology of nouns (declension), English is an analytic language. It does not grammatically code cases (e.g. accusative) which makes word order, i.e. the linearity of elements (phrases/groups) in utterances or sentences essential. Nevertheless, English nouns mark number (singular or plural) and are congruent with the verb in terms of number when the noun (phrase) is the subject of the sentence. However, there are three plural nouns in the text (*conditions* (8), *side effects* (8), *patients* (11)). All of them have a regular plural form which is built by adding the suffix *-s* to the nominal stem.

For the inflectional morphology of adjectives, the following needs to be mentioned. The comparative and superlative forms of adjectives are marked. Regular forms (e.g. *fast*$_{\text{positive}}$ – *faster*$_{\text{comparative}}$ – *the fastest*$_{\text{superlative}}$) are built by adding the suffix *-er* (comparative) or *-est* (superlative) to the adjective stem. The superlative also needs the definite article *the* in addition, as there is only one maximum, i.e. the superlative is inherently definite. In (7) there is the noun phrase (NP) [*a better recovery*]. Here the comparative form of the adjective *good* (positive) is irregular (*better*). This is a suppletive form (suppletion). In (8) there are two comparative forms (*[…] the sooner the drug is given the more effective it is*). The adjective *effective* has three syllables (*ef.fec.tive*). This is the reason why instead of adding the suffix *-er* to the adjective stem for building the comparative form *more* is used and *the most* for the superlative (ef.fec.tive$_{\text{positive}}$ – more ef.fec.tive$_{\text{comparative}}$ – the most ef.fec.tive$_{\text{superlative}}$). (8) is a complex sentence (*We know that the drug reduces bleeding in other types of haemorrhage conditions, without side effects, and [we know that]*$_{\text{analepsis}}$ *the sooner the drug is given the more effective it is*). We will only focus on the use of the comparative forms here. Both comparative forms are fronted by the definite article *the*. The first clause (*the sooner the drug is given […]*) expresses a condition or cause. The second clause (*the more effective it is*) expresses the result or effect of the condition/cause coming true. At the same time, it realises a comparison. On an abstract level it can be described as follows: the modification of the amount of x leads to the modification of the amount of y. There is an interdependency between the two elements (the modification of the amount of x leads to the modification of the amount of y). The two amount modifications – which are a comparison in terms of a deviation from a neutral default, but not to the most extreme extent – are conceptualisations of a scale. A specific form is even highly lexicalised as an idiom (*the more the merrier*). These structures point to a frequently perpetuated, i.e. used way of thinking. Also, as forms of collective knowledge idioms like *the more the merrier* are instances of linguistic realisations of a specific knowledge

[5] We won't deal with (26) here in greater detail.

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structure type which Ehlich and Rehbein dubbed *Sentenz* in German (Ehlich and Rehbein 1977). According to Ehlich and Rehbein these knowledge structures fulfil functions which are related to the organisation and the use of knowledge in institutional as well as in everyday actions (*ibid.*: 57).

2.1.5. Prepositions

There are 13 different prepositions in the short patient information sheet: (i) *about* ((13), (15), (16)), (ii) *at* ((4)), (iii) *by* ((3), (10)), (iv) *for* ((2), (4), (17), (18)), (v) *in* ((3), (5), (8), (9), (11), (13)), (vi) *inside* ((6)), (vii) *into* ((10)), (viii) *of* ((2), (8), (10), (12), (14)), (ix) *over* ((10)), (x) *to* ((7), (13), (14)), (xi) *until* ((12)), (xii) *with* ((17)), (xiii) *without* ((8)). They are complex in various respects. Here we focus on the meaning of prepositions. They express specific relations. Basic spatial prepositions locate an object in reference to another object in space (Grießhaber 1999). From the perspective of cognitive semantics, spatial relations are basic relations in conceptual terms. Other, more abstract relations are abstractions of these basic concepts. However, an interesting structure is the combination of the comparative *more* with the preposition *about* ((*to know/tell* x_{NP} *more about* y_{NP}). This combination is ruled by the verb (valence) which points to an asymmetry of knowledge (*x knows something/more about y*, *x tells z something/more about y*). The meaning of prepositions can only be understood by understanding the relations they convey. Hence, the phrasal structure they are embedded in also plays an important role. We will elaborate on this point when dealing with the phrase/sentence level. The preposition *at* is used to express a spatial relationship (closeness). In both instances *by* follows an infinite verb form (past participle): *caused/followed by x*. In two cases ((17), (18)) *for* is used in a rather odd way: *to be happy for* x_{person} *to go ahead with* y_{action}. The preposition *in* expresses various abstraction levels of the concept of containment. *Inside* is a lexicalised compound preposition (*in-side*) which also expresses containment. *Into*, also a lexicalised compound preposition (*in-to*), combines the two spatial relations of (i) containment (*in*) and (ii) (enclosed) target area (*to*). In all instances the prepositional phrase (PP) with the head *of* functions as an attribute to the head of a noun phrase (NP); *of* is highly grammaticalized, so that it has undergone semantic bleaching. Its meaning can be determined by the specific use and its function in constituents of a higher hierarchical order. The preposition *over* expresses a temporal relation, not a spatial relation and is therefore a (first order) abstraction in its use in the text. *To* has different levels of abstraction. It refers to (i) a target area (spatial relation, (13)), (ii) a state or process ((7)), or – in combination with the adjective *similar* – a comparison ((14)). Another temporal relation is put forward by the preposition *until*. Whereas *with* expresses the presence of someone or something, *without* is a lexicalised compound preposition (*with-out*) which is the opposition of *with* and refers to the relation of someone or something being absent.

2.1.6. Quantifiers

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The text contains several quantifiers. *All* ((4)) refers to a totality, i.e. a universe of entities. The quantifier *half* divides a universe of entities by two. *Some* is unspecific, i.e. it does not refer to a specific quantity, and *one* refers to a single entity. The indefinite article *a/an* is used six times ((5), (6), (7), (10), (11), (13)). When a new topic is introduced in text or discourse[6], an indefinite NP is used. After its introduction definite NPs are used, as the topic (and reference) is known to the reader or listener (Hoffmann [2]2014). The definite article *the* is used ten times ((3), (4), (6), (7), (8), (10), (11), (12), (14), (17)). An important function of the definite article is determination. For example, in (6) tranexamic acid is introduced as a drug. Here an indefinite NP is used (***a** drug called tranexamic acid*). In the following sentence ((8)) the definite article *the* is used, as the topic is now known to the reader (***the** drug*).

2.1.7. Technical terms

The text contains four technical terms: (i) *tranexamic acid* ((2), (6), (11)), (ii) *haemorrhage stroke* ((2), (3), (6), (9)), (iii) *TICH2* ((2)), and (iv) *CT brain scan* ((14)). These terms are potentially unknown to laymen. *Tranexamic acid* is a compound noun and can be classified as technical terminology (jargon). *Haemorrhage* (in *haemorrhage stroke*) is of Greek (and later Latin) origin. *TICH2* is an acronym (*tranexamic acid for hyperacute primary intracerebral haemorrhage*). Also, the complex compound noun *CT brain scan* contains an acronym (*CT = computer tomography*).

2.1.8. Summary: word level

On the word level there is some complexity which might not be obvious at first sight – especially for linguistic laymen. Measures such as the fog index are rather quantitative measures. They do not consider the quality and function of words (in context).

Regular compounds express specific relations between at least one modifier and the compound's head. The personal deictic expressions *you* and *I* serve the purpose of the institutional form. First, they address the patient and potential subject with the expression *you*, then the perspective of the patient is taken when she/he is expected to give her/his legal consent (*I*). Figurative language is also used. Four different tenses are used ((i) present tense, (ii) present perfect tense, (iii) past tense, (iv) *will*-future). The text features comparative forms, a variety of prepositions which express different basic and more abstract relations. Finally, quantifiers and technical terms can be found in the brief patient information sheet as well. All these word level phenomena contribute to the text's complexity and can potentially cause comprehension difficulties.

2.2. Phrase/sentence level

[6] *Discourse* is understood as an oral communication situation (Ehlich 1984).

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On the phrase and sentence level we will take a closer look at (i) syntax and (ii) technical phrases/constructions, i.e. constituents of sentences which are typical for technical language use.

2.2.1. Syntax

In this subcategory we will take a closer look at (i) analepses/ellipses, (ii) complex phrases, (iii) conditional clauses, (iv) parentheses, (v) subordinate (and relative) clauses, and (vi) yes-no questions.

There are three analepses in the text. The first one can be found in (8) (*We know that the drug reduces bleeding in other types of haemorrhage conditions, without side effects, and [we know that]*$_{\text{analepsis}}$ *the sooner the drug is given the more effective it is*). *We* is the subject of the first as well as the second sentence. The lexical verb *know* (1st person plural, present tense) is the verb of the main clause of sentence 1, and it is also the verb of the main clause of sentence 2. The verb *know* is a transitive verb; it needs a direct object (x_{subject} *knows*$_{\text{3rd person singular, present tense}}$ $y_{\text{direct object}}$). The conjunction *that* fronts a subordinate clause in sentence 1 ([*that the drug reduces bleeding in other types of haemorrhage conditions*]). This whole unit (the subordinate clause introduced by the conjunction *that*) functions as a complement (here: the direct object) to the verb *know* ([*We*]$_{\text{subject}}$ [*know*]$_{\text{verb}}$ [*that the drug reduces bleeding in other types of haemorrhage conditions*]$_{\text{verb compliment, direct object}}$. To our understanding this structure is duplicated, but not linguistically realised, i.e. made explicit on the linguistic surface by linguistic means.[7] It is cognitively challenging, as the reader needs to bear in mind that the assertion or proposition of the main clause (*We know x*) is valid for the assertion/proposition of the next subordinate clause ([*We know*]$_{\text{main clause}}$ [*that the drug reduces bleeding in other types of haemorrhage conditions,*]$_{\text{subordinate clause1}}$ [*without side effects*]$_{\text{parenthesis}}$ [*and*]$_{\text{coordinating conjunction}}$ [*we know*]$_{\text{analepsis}}$ [[*that*]$_{\text{analepsis}}$ *the sooner the drug is given the more effective it is*]$_{\text{subordinate clause2}}$). [8] In (8) the (scientific) knowledge about tranexamic acid is verbalised. In (9) the knowledge deficit is formulated. This missing knowledge is also the reason why this specific clinical trial is scientifically relevant.

Analepses can also be found in (11) (*Half [of] the patients in the study will get the tranexamic acid and half [of the patients in the study]*$_{\text{analepsis}}$ *[will get]*$_{\text{analepsis}}$ *a dummy drug […]*). Here, the NP [*half [of] the patients in the study*] is the subject ([*half* [[*the patients*]$_{\text{NP}}$ [*in* [*the study*]$_{\text{NP}}$]$_{\text{PP}}$]$_{\text{NP}}$]$_{\text{NP}}$). The head *half* is modified by the information provided in the subordinate phrases, so that it is clear to the reader which half the assertion is about. As this is specified in the first main clause of (11), the complete NP does not need to be repeated for the second main clause of the sentence in (11) which starts after the coordinating conjunction *and*. Now

[7] In the case of an analepsis the reader (or listener in oral communication) knows the topic being discussed from the co(n)text and can build references (e.g. *There is a yellow car. It is fast and [it is] loud* or *The black cat caught a mouse and [the black cat] ate it*).

[8] To our understanding sentence 2 is [[*we know that*]$_{\text{analepsis}}$ *the sooner the drug is given the more effective it is*]. The subject *we*, the finite verb of the main clause *know*, and the subordinating conjunction *that* are (deliberately) left out.

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it is enough to just use the head *half*. As the verb *will get* (*will*-future) is also valid for the second main clause of the sentence in this unit, it needs no linguistic realisation either (*[…] and half [of the patients in the study] [will get]*$_{\text{analepsis}}$ *a dummy drug […]*). This is an economic principle that these elements don't need to be repeated, as they have been previously verbalised. However, this might increase the cognitive load for the reader, as she/he needs to keep the knowledge which the analepsis transports and refers to (i.e. a specific theme/topic) activated to understand correctly what is meant.

A third analepsis is in (13) (*We will need to collect some information about your medical condition and [we will]*$_{\text{analepsis}}$ *send it to a central office in Nottingham*). The two main clauses are connected by the coordinating conjunction *and*. *We* is the subject in both main clauses. Also, the finite (auxiliary) verb *will* is still valid for the second main clause. Subject and finite verb are not repeated, as it is clear that both assertions are about the referent(s) of the term *we* and refer to a future action (*will*-future).

The text document features several complex phrasal structures (the head of each phrase is underlined). In (3) there is a complex NP ([*a haemorrhagic stroke […] that needs urgent care*]) which is the direct object. A parenthesis which is a complex NP itself is embedded ([*a stroke caused by bleeding in the brain*]). Another complex NP can be found in (4) ([*all the usual emergency care for stroke that we provide at this hospital*]). This NP is also the direct object. More complex NPs are to be found in (8) and (10) ((8): [*other types of haemorrhage conditions*], (10): [*an injection into a vein followed by a drip over eight hours*]). The NP in (10) functions as the direct object, whereas the NP in (8) is embedded in a prepositional phrase (PP) which is an adverbial. The NPs in (11) and (13) can also be mentioned here ((11): [*half the patients in the study*], (13): [*some information about your medical condition*]). The complex NP in (13) is the direct object, whereas the NP in (11) is the subject.

From (2) to (18) every sentence contains at least one PP. We won't go through each of them here but just point out some cases. In (6) the NP [*bleeding inside the head*] contains the PP [*inside the head*]. This PP is immediately followed by another PP in this very same text unit ([*after haemorrhagic stroke*]). Whereas the first PP ([*inside the head*]) modifies the head of the NP it is embedded in (*bleeding*), the following PP ([*after haemorrhagic stroke*]) is an adverbial which is independent from the NP [*bleeding inside the head*]. Other PPs in the text contain another subordinate PP themselves ((8), (10), (12), and (13)). For example, in (8) the PP [*in other types of haemorrhage conditions*] contains the subordinate PP [*of haemorrhage conditions*]. As prepositions convey some kind of relation between entities (word level), this might also cause difficulties in (a) understanding parts of the text and (b) respectively the complete text.

We won't focus on the syntactic structures of verb phrases (VPs) here in detail, as their main syntactical complexity is contributed by their NPs which (a) we have covered above to some extent and (b) function as complements (direct or indirect object, subject). Instead, we only want to mention the following structures. In (5), (14), and (15) the VP [*x would like to* LEXICAL VERB$_{\text{infinitive form}}$ *y*] is used (*[…] we would like to include you in […]* (5), *We would also like to perform*

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one additional CT brain scan […] (14), *[…] you would like to know more about it […]* (15)). Although the VP [*would like to* + LEXICAL VERB$_{\text{infinitive form}}$] is lexicalised, it might cause comprehension challenges for a person who has just suffered a stroke.

There are several subordinate clauses in the text. Relative clauses are also subordinate clauses. We understand the structures in (3), (6), and (10) as ellipses and therefore also as relative clauses (*a stroke [which is]*$_{\text{ellipsis}}$ *caused by bleeding in the brain* (3), *a drug [which is]*$_{\text{ellipsis}}$ *called tranexamic acid* (6), *an injection into a vein [which is]*$_{\text{ellipsis}}$ *followed by a drip over eight hours* (10)). There is another relative clause in (3) ([*a stroke caused by bleeding in the brain that needs urgent care*]$_{\text{NP}}$). Also, in (4) there is a relative clause ([*all the usual emergency care for stroke that we provide at this hospital*]$_{\text{NP}}$). What can be seen is that these NPs are made complex by several modifiers. This might cause comprehension problems. The knowledge that these assertions transport is crucial for the patient to understand her/his situation, to get relevant information, and to consent to participating in the study. Subordinate clauses are also used in (7), (8), (9), and (12). In these cases, they are governed by the verb. The subordinate clauses function as the direct object (*We hope [that the drug will lead to a better recovery]*$_{\text{subordinate clause, verb complement (direct object)}}$ (7), *We know [that the drug reduces bleeding […]]*$_{\text{subordinate clause, verb complement (direct object)}}$ (8), *[…] and [we know [that]]*$_{\text{analepsis}}$ *the sooner the drug is given the more effective it is]*$_{\text{subordinate clause, verb compliment (direct object)}}$ (8), *we don't know [if it works in haemorrhagic stroke]*$_{\text{subordinate clause, verb complement (direct object)}}$ (9), *We won't know until the end of the study [who received which treatment]*$_{\text{subordinate clause, verb compliment (direct object)}}$ (12). The abstract structure in these cases is as follows: [[*x*]$_{\text{subject}}$ [*(don't) hope/know* [*y*]$_{\text{direct object}}$]$_{\text{VP, predication}}$]$_{\text{sentence}}$; *y*'s position is filled by a subordinate clause which is introduced by the subordinate conjunction *that* ((7) and (8)) or *if* ((9)) or by the pronoun *who* ((12)).

There is one conditional clause (type I) in the text: *If you would like to know more about our study now […]* ((15)). Within the *if*-clause the present tense is used. *Would* is part of the lexicalised verb phrase *would like to LEXICAL VERB*$_{\text{infinitive}}$ (here: *x would like to know y*). In the main clause *will*-future is used (*[…] then we will tell you*). This combination is often referred to as *if*-clause type I.

In (8) the sentence *[…] the sooner the drug is given the more effective it is* also has – to our understanding – a conditional component in the sense that it can be paraphrased as follows: *if action x is performed in a way in which factor a is modified, then factor b which is related to the performed action x is modified in a specific way as well*. This interdependency can be conceptualised as conditional.

In (14) there is a final clause (*We would also like to perform one additional CT brain scan […] [in order] to monitor the effect of the treatment*). This is a dependent (adverbial) clause which expresses purpose.

One phenomenon which makes the text more difficult to understand is the use of parentheses. This is a structure (a word, phrase, or sentence) which is inserted to the (main) utterance or sentence to add an idea, etc. The utterance or sentence is (grammatically) complete without the parenthesis. Often commas or parentheses, i.e. brackets are used to mark it. In the text there are four instances of parenthesis in total ((3), (8), (11), and (14)). In (3) the direct object

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of the verb, i.e. the NP [*a haemorrhagic stroke (*[*a stroke caused by bleeding in the brain*]$_{\text{NP, parenthesis}}$*) that needs urgent care*]$_{\text{NP, direct object}}$ features a parenthesis (the underlined part). It follows the NP [*a haemorrhagic stroke*]. This technical term might be unknown to medical laymen. For this reason, the authors decided to add a parenthesis to provide a brief definition of the technical term. To mark this parenthesis, brackets are used. In (8) the parenthesis – here marked by commas – adds an idea to the assertion of the sentence *We know that the drug reduces bleeding in other types of haemorrhage conditions*. Here the information is added that the drug doesn't have any side effects (*[…], without side effects, […]*). This is an extremely relevant piece of information for the patient, so it would be helpful for the whole purpose of the text document to use a complete statement in form of a sentence instead, e.g. *The drug does not have any side effects in the context of known applications*. In (11) there is another parenthesis: *[…] and half [the patients in the study will get]*$_{\text{analepsis}}$ *a dummy drug (a liquid which does not contain tranexamic acid)*. After the coordinating conjunction *and* the NP [*a dummy drug*] functions as the direct object (verb complement). The authors decided (i) not to use the term *placebo* here, (ii) to define what *dummy drugs* means. The definition of *dummy drug* is linguistically realised by a parenthesis. Its beginning and its end are marked by brackets. The parenthesis consists of a complex NP ([*a*$_{\text{indefinite article}}$ *liquid*$_{\text{head noun}}$ [*which*$_{\text{relative pronoun}}$ *does*$_{\text{auxiliary verb, 3rd person singular, present tense}}$ *not*$_{\text{negation particle}}$ *contain*$_{\text{lexical verb, infinitive form}}$ *tranexamic*$_{\text{adjective}}$ *acid*$_{\text{noun}}$]$_{\text{relative clause}}$]$_{\text{NP}}$). Finally, a parenthesis can also be found in (14). It is also indicated by brackets (*We would also like to perform one additional CT brain scan (similar to the one you had to diagnose your stroke) to monitor the effect of the treatment*). Here the NP [*one additional CT brain scan*]$_{\text{verb complement, direct object}}$ gets additional information by pointing out that this additional CT brain scan is like the one that was carried out for diagnosing the stroke. *Similar to* is used to express a comparison. The additional brain scan which needs to be done in the context of the study is compared to the CT brain scan which was carried out to diagnose the stroke. Hence, the patient and potential study subject is provided with the information that this procedure is already part of her/his (experience-based) knowledge.

In (26) the instruction *Complete only where required* is verbalised. Although it is also marked by brackets, this is not a parenthesis. It is only relevant for text units (19) to (25). The reader needs to read the whole document first to read this instruction which is linguistically realised as an imperative sentence. We suggest placing it in front of the relevant text units instead. The instruction has a text structuring function and an influence on the reading process.

The text contains a yes-no question in (17) (*Are you happy for us to go ahead with the study treatment?*). The copular verb *are* is used in initial position. In assertive sentences (declarative/indicative mood) the finite verb is in the second position and follows the subject. In yes-no questions (interrogative mood) the finite verb is fronted (first position) (like in imperative mood), the subject follows the fronted finite verb. This change of word order should usually cause no comprehension difficulties – under normal circumstances. However, it might add complexity to the text as well, as word order is crucial in English. Also, it marks a functional shift from the purpose of informing the potential study subject about

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his/her condition as well as the study to obtaining her/his consent for being enrolled in the study. For reasons of research ethics, the individual reader should be asked first whether she/he has understood the information conveyed or not.

2.2.2. Technical language use

Phrases which are typical for technical language use can be found in (3), (6), (8), and (10). This is not a complete list. We rather want to point out here that there are structures on the level of phrases that can be classified as typical for language for special purposes contexts. In (3) the NP of the parenthesis (*a stroke caused by bleeding in the brain*) can be abstracted as follows: *x caused by y*. To our understanding this is a typical structure to refer to causes. As pointed out above, the parenthesis has the function to define the NP [*a haemorrhagic stroke*]. This term denotes a specific (medical) concept. It can be understood as the result of (physiological) processes that lead to a specific medical condition. To understand this condition denoted by the term the cause for the condition is provided by using the structure *x caused by y*. As we suggested above, this structure can be analysed as an ellipsis (*x [which is]*$_{\text{ellipsis}}$ *caused by x*). Then it is a passive construction. The passive voice is also used in the context of technical language. Its function is to background the agent. In (8) the passive voice is also used (*the sooner the drug is given the more effective it is*). The structure in (8) can be abstracted as follows: [[*the ADJ*$_{\text{comparative form}}$ *x*]$_{\text{constituent1}}$ [*the ADJ*$_{\text{comparative form}}$ *y*]$_{\text{constituent2}}$]$_{\text{complete structure}}$ (also word level, (inflectional) morphology). It can be paraphrased as follows: if the comparative form of the adjective in constituent 1 is modified, it influences the comparative form of the adjective in constituent 2. Hence this structure is used to express an interdependency which can be classified as a cause-effect relation. Other structures related to technical language use can be found in (6) and (10). In (6) the abstracted structure *x called y* is used (*a drug called tranexamic acid*). Here the technical term *tranexamic acid,* which is most probably unknown to laymen, is categorised. The more specific technical term is classified as a drug. The concept of DRUG is broader and known from ordinary everyday contexts. In structures of this form the first element *x* provides a (superordinate) category to classify the second element *y* as a category member. This categorisation serves the demand to define the referent of the expression of the second element (*y*, here: *tranexamic acid*). According to our understanding laid out above, this is also an ellipsis (*a drug [which is]*$_{\text{ellipsis}}$ *called tranexamic acid*). Therefore, it is also a passive structure (*x (RELATIVE) PRONOUN is called y*). This is also the case for the structure in (10). The NP [*an injection into a vein [which is]*$_{\text{ellipsis}}$ *followed by a drip*] also contains the passive voice. It can be abstracted as follows: *x* [relative pronoun + finite auxiliary verb]$_{\text{ellipsis}}$ *followed by y*. It is used to express a process, more specifically a sequence (of actions).

Many of these structures mentioned here are used in everyday communication and are common everyday linguistic structures. They have the potential to be applied for specific academic, scientific, or technical language

purposes. Ehlich uses the German expression *alltägliche Wissenschaftssprache* to refer to such structures (Ehlich 1999).

2.2.3. Summary: phrase/sentence level

There are several phenomena on the level of phrases, clauses, and sentences which add complexity to the text and make it potentially more difficult to understand for the reader. There is a relevant number of analepses and ellipses, complex phrases, subordinate, relative, and conditional clauses, and parentheses which is not covered by instruments such as the fog index to calculate the readability of texts. This more detailed linguistic analysis considers a variety of linguistic phenomena on different analytical levels to better understand which linguistic challenges it holds for readers, i.e. patients and potential study subjects. In addition to the already mentioned phenomena there is also a yes-no question which has a different word order compared to an assertion. Also, the text contains various structures that can be described as technical language structures. In particular, these structures in combination with parentheses, subordinate, relative, and conditional clauses as well as complex NPs increase the challenge for the reader to understand everything in a non-ordinary comprehension situation.

2.3. Text level

The text level exceeds the boundary or scope of phrases and sentences. A (written) text can be understood as a sequence of linguistic actions which are produced in a speech situation which is different from the speech situation in which they are perceived. Text is a linguistic means to bridge the gap between both situations. There is no spatio-temporal co-presence of speaker (S) and hearer (H)[9] (or of an author and a reader), i.e. immediate (and comprehension ensuring) communication between S and H is not possible (Ehlich 1984). This is why a text needs to be very explicit and elaborate. It is the result of S's action plan (Rehbein 1977). The configuration of the action constellation in the case of the brief patient information sheet is complex (Rehbein 2001). It is a discourse situation in which the patient is handed a text document. A discourse is an oral communication situation which is characterised by the co-presence of S and H. This means that direct oral communication between them is possible. The physicians who treat the patient are not the authors of the text document, but they surely can provide relevant information to the patient. They can talk to each other. However, the patient is supposed to read through the document and give her/his consent to be enrolled in the study. The patient needs to read a written text, but she/he can also ask comprehension questions directly. This shows that the text document serves the institutional purpose of getting legal consent. It has a legal communicative function for the institution (the research facility).

[9] "Speaker" and "hearer" are abstract concepts. They are not used in combination with an article.

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On the level of text, we will deal with (i) coherence: introduction, continuation, and development of a topic, (ii) linguistic action patterns, (iii) perception conditions, (iv) text connectivity (means of text structuring, etc.), (v) text continuity (reader-text interaction), text deixis, and text type.

2.3.1. (Thematic) coherence: introduction, continuation, and development of a topic

Fix (2008) defines *coherence* as the thematic relations of or in a text which reach beyond the level of sentences (Fix 2008: 75). To his understanding coherence includes thematic, structural, and grammatical aspects (*ibid.*). Grammatical coherence is often referred to by the term *cohesion*. In our analysis we will focus on thematic coherence.[10]

Hoffmann defines *topic* (or: *theme*) as the subject or issue which is continuously talked about in a discourse or text (Hoffmann 2014: 178). Five main topics can be identified in the brief patient information sheet: (i) the drug (tranexamic acid), (ii) the patient, (iii) the researchers, (iv) the study, and (v) the stroke. Topic 1 (the drug) is introduced in (6) (*a drug called tranexamic acid*). When a new topic is introduced, the NP is indefinite. Once this information is mentally present for both interlocutors, it is integrated into the knowledge of S and H, present, and accessible. In (2) the name of the drug is mentioned in the title of the document (*Tranexamic acid for Haemorrhage Stroke (TICH2)*). But it is no earlier than in (6) when the reader gets to know that *tranexamic acid* is a drug. After the introduction of the topic definite NPs or anaphors are used to continue the topic in the text, i.e. to refer to the now known topic. In (7) and (8) the definite NP [*the drug*] is used. In (8) and (9) the anaphor *it* continues topic 1 (the drug) and creates thematic coherence on the text level ((8): *[…] the more effective it is*, (9): *[…] we don't know if it works […]*). The definite NP [*the tranexamic acid*] continues topic 1 (the drug) in (11). From (10) to (14) the process of the study is described. It is mentioned that giving tranexamic acid to half of the enrolled patients is an essential part of the study ((11)). Some patients will receive a so-called dummy drug; the other half will receive the tranexamic acid ((11)). Here a distinction is made between *the study treatment* ((17)) and *treatment* in general (*treatment* (12), *the treatment* (14)), as all the enrolled patients will get a specific study treatment, but only half of them will get the tranexamic acid. Hence, *study treatment* can also be analysed as a continuation of topic 1 (the drug). Topic 2 (the patient) is mentioned thirteen times in the text document ((1), (3), (4), (5), (10), (11), (12), (13), (14), (15), (16), (17), and (18)). First it is introduced in (1), the title of the text document (not the title of the text): *Brief Patient Information Sheet*. After that the personal deictic expression *you* is used to personally address the patient, i.e. the reader ((3), (4), (5), (10), (15), (16), and (17)). Topic 2 is also continued in (11) (*Half the patients in the study […]*), in (12) with the pronoun *who* which has an anaphorical function, in (13) with the NP [*your medical condition*], in (14) with the NP [*your stroke*], and in (18) with the personal deictic expression *I*. Topic 3 (the researchers) makes use of personal

[10] Givón also provides a study on topic continuity in discourse (Givón 1983).

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deictic expressions (*anadeixes*). *We* is used in (4), (5), (7), (8), (9), (12), (13), (14), (15), and (16). In (17) *us* is used to continue topic 3. In (18) *you* is used. The shift of perspective is linguistically realised using *I* in reference to the patient (continuation of topic 2) and the use of *you* in reference to the researchers (and medical staff) as a continuation of topic 3. Topic 4 (the study) is first mentioned in (2): *Title of Study*. It is then introduced in the text in (5) (*an international study*) and continued in (6) (*This study […]*), (10) (*As part of the study […]*), (11) (*Half the patients in the study […]*), (12) (*[…] the end of the study […]*), and (17) (*[…] the study treatment*). Text units (1) and (2) are likely to be used for internal information only, i.e. it is possible that the document is used in such a way that only the title (*Tranexamic acid for Haemorrhage Stroke (TICH2)*) and the rest of the text document are printed on paper and given to the patients. However, (5) functions as an introduction of topic 4 (the study). The NP [*an international study*] is indefinite. After this introduction topic 4 is continued with the definite article. Only in (6) the definite deictic determiner *this* is used instead of the definite article *the*. Topic 5 (the stroke) is first mentioned in (2) (*Tranexamic acid for Haemorrhagic Stroke*). It is introduced as a topic in the text to the reader in (3): [*a haemorrhagic stroke (a stroke caused by bleeding in the brain)*]$_{\text{indefinite NP}}$. Topic 5 (the stroke) is then continued in (4) (*[…] all the usual emergency care for stroke […]*), (6) (*[…] after haemorrhagic stroke*), (9) (*[…] in haemorrhagic stroke*), and (14) (*[…] to diagnose your stroke […]*).

2.3.2. Linguistic action patterns (supra-sentential illocutive units)

Linguistic action patterns are interaction resources (Ehlich 2010: 218). They are societally (and historically) elaborated forms of linguistic action which serve the purpose of dealing with recurring communicative tasks in a society and its institutions (Ehlich 2000: 188–189). A linguistic action pattern is organised by its illocution, i.e. the communicative purpose it serves. It needs to be reconstructed, as it is a deep structure which is not directly realised on the linguistic surface (*ibid.*). In contexts of knowledge transfer, DESCRIBING and EXPLAINING are commonly used linguistic action patterns – often in combination (Sotkov and Frank 2021; Beckmann 2017). In the brief patient information sheet, there is a process description (linguistic action pattern: DESCRIBING) from (10) to (14). In (5) the international study is introduced as a topic. In (6) the main research question is verbalised. In (7) the potential benefit of the study, the anticipated outcome is formulated. In (8) the scientific knowledge about the research object is explicitly verbalised. In (9) unknown knowledge elements are mentioned. Thereby the reason why this study needs to be carried out is given. From (10) to (14) the study process is described to the patient. In (15) the patient gets the chance to ask questions about the study (process). In (16) the patient is informed that she/he will get more information later.

According to Hoffmann (2014) the purpose of DESCRIBING is that H can form a mental image or representation of the described object or process, so that H can link formal and functional aspects to it (Hoffmann 2014: 521). The process description which starts in (10) is introduced by the text structuring adverbial

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As part of the study […] ((pre-)prefield). The patient is informed (i) that she/he will get an injection and a drip, (ii) that she/he will be either part of the group which receives the tranexamic acid or the group which receives a placebo, (iii) that the researchers don't know which patient is part of which group, (iv) that they need some information about the patient's medical condition, and (v) that they want to perform one additional CT brain scan. The patient's role in the institution is manifested in the focus on the perspective of the researchers, i.e. what they want to do with the patient in the context of the study. Only once is the patient's perspective taken – in (10) (*[…] you will receive an injection […]*). In all other formulations in the frame of the description the perspective of the medical researchers is taken ((*We won't know […]* (12), *We will need to collect […]* (13), *We would also like to perform […]* (14)). In (11) neither is the patient directly addressed nor is the perspective of the researchers explicitly verbalised (*we*). One can argue that here the most scientific part of the text document can be found, as the formulation is rather neutral, objective and refers to the methodological procedure of the clinical trial. However, this focus on the perspective of the institutional agents (researchers (*we*)) transports the notion that the patient's agency, i.e. her/his scope of (linguistic) action is very limited. These power relations and institutional roles are displayed, but also partially established and maintained through language.

2.3.3. Perception conditions

The focus of the patient's attention lies obviously on her/his current condition. It is an extremely time-sensitive and emotional situation. Due to the stroke, impairments can (temporally) occur. This means that the patient's comprehension abilities might be affected to some extent. Also, stroke patients are usually older than 13 or 14. They have different knowledge resources than children who are the base for calculating the text's readability (the fog index assumes that a text is appropriate and comprehensible if 13- to 14-year-olds can understand it).

Data on the individual language biographies of the patients would be very helpful. It is of enormous importance for the modelling and operationalisation of readability whether the English language is the patient's first language (L1) or a second or foreign language (L2). But even within the same category (L1 or L2) the language skills of persons usually vary to some extent. Research is needed on the reading comprehension of real patients. Only on such a basis it can be understood whether such documents are appropriate and comprehensible or not. A functional linguistic analysis of these text documents is needed but also the linguistic abilities of the patients need to be considered systematically.

2.3.4. Text connectivity (means of text structuring)

There are some means of text structuring in the text. In (5) the subject and the predicate are fronted by the conjunct (adverbial) *As well as this […]* which has the function to express that the subsequent information adds to the preceding

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information, i.e. the assertion (information) provided in (4). In this sense the conjunct connects the two sentences and creates connectivity on the text level. In (8) a statement is made on what is scientifically known about the use of tranexamic acid in the context of haemorrhagic conditions. In (9) the current scientific knowledge deficit is verbalised in reference to the use of the drug for haemorrhagic strokes. The (temporal) conjunct *As yet […]* precedes the subject *we* and the predicate of the sentence (*[…] don't know if it works in haemorrhagic stroke*). First, the status quo on this subject matter is stated, then what still needs to be achieved is verbalised. This has a temporal component in the sense that (from the reference time of reading the text for the first time) the (future) results of the clinical trial might help close the mentioned scientific knowledge gap. In (10) the description of the study measures is explicitly introduced by the adverbial *As part of the study […]* before the subject *you* and the predicate *[…] will receive an injection into a vein followed by a drip over eight hours*. It has a category inclusion function (*you as a part of the study*), i.e. the role of the patient as a study participant is verbalised. Interestingly, it exerts a forward-orientated function in the text, as the mental situation which is activated (study measures, processes of the study) stays valid until (14). It is like the left bracket for the linguistic action pattern DESCRIBING in the text. There is no explicit closing bracket. Instead, there is a cut made in (15). The reader is informed that the researchers will provide more information if she/he asks for it. This is followed by another conjunct at the beginning of (16): *But otherwise […]*. Although in terms of research ethics this is a default procedure to inform the participants in more detail after the study, one could get the impression here that the text at this point shuts down the patient as a communication partner. It limits the patient's possibilities to (communicatively) act and forces the institutional processing of the patient.

2.3.5. Text continuity (reader-text interaction), text deixis, and text type

As there is not much to say about these individual categories for this specific text, they are dealt with together.

It is a continuous text, i.e. it does not contain any charts, tables, etc. which influence the readers eye movements, attention, her/his interaction with the text. Illustrations can facilitate text comprehension, but they can also add complexity to a text.

There is one anadeictic expression ("object deixis") in the text (*As well as this […]* (5)). It refers to the information provided in (4) (the statement that the patient will get the default emergency care for stroke (with the limitation *that we provide at this hospital*)). It is not a thematic progression of a NP but of a whole sentential unit. The reader needs to understand this reference link correctly.

In terms of its typological classification the text can be characterised as a standardised and institutional text with a specific ethical and legal function. It combines elements of providing sufficient information to institutional clients ((stroke patients as potential) research subjects) and legal aspects. The text is not a standardised text of hospitals (the medical institution) for the purpose of

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processing institutional clients (patients). It is a standardised text of academic research facilities which is obligatory due to ethical reasons. It is a legal and ethical obligation to get the informed consent of study participants. If study participants don't understand the provided information correctly or at all, they cannot give an informed consent. We understand *informed* not only in the sense of providing information at all but making sure that the information is understood.

2.3.6. Summary: text level

The text contains five main topics ((i) the drug (tranexamic acid), (ii) the patient, (iii) the researchers, (iv) the study, (v) the stroke) which contribute to its (thematic) coherence. The linguistic action pattern DESCRIBING is used to create a mental representation on the side of the reader (the patient) about what it is like to participate in the study (processes are described). In terms of the perception conditions not much is known about the linguistic abilities of the patients (including reading comprehension skills). Also, it is not clear whether the patients have experiences with standardised institutional texts (here: an information sheet and consent form). It is likely that patients don't have daily encounters with this specific text type. This inexperience or lacking routine in dealing with such texts might lead to comprehension difficulties. Furthermore, it is a very special and emotional situation for the patients. Other text level phenomena which can potentially make the comprehension of the text more difficult are (i) the anadeictic expression *this* ((5)) which refers to the assertion of the preceding sentence and needs to be kept active in short-term memory and (ii) means of text structuring which contribute to text connectivity (e.g. the adverbial (conjunct) *As well as this […]* in (5)). The text is continuous, i.e. no diagrams, charts, etc. are used. This makes the reader-text interaction more straightforward. At the same time diagrams, charts, etc. have the potential to facilitate understanding.

All in all, there are several complex linguistic phenomena on the level of text (super-sentential level) which a functional linguistic analysis can unveil.

3. Proposal for an improved brief patient information sheet and consent form

Based on the linguistic analysis we propose the following modified text.

> **Patient information sheet and consent form for the study "Tranexamic acid for Haemorrhage Stroke (TICH2)"**
>
> **What happened?**
> You have had a stroke. A stroke is a medical emergency. Bleeding in the brain caused your stroke. This type of stroke is a haemorrhagic stroke.
> Your condition needs urgent medical care.
>
> **Which treatment will I get?**

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You will get the usual emergency care for stroke at this hospital.

Why am I reading/hearing this information?
We (the researchers) seek your consent. We want to include you in an international study.

What do you want to find out with your study?
Our main research question is the following. Does a specific drug reduce bleeding in case of a stroke like yours? The drug (tranexamic acid) might lead to a better recovery. We want to understand and measure the effect of the drug.

What do you know about the drug (tranexamic acid)?
(1) The drug reduces bleeding in other types of haemorrhage conditions.
(2) It does not have any known side effects.
(3) Time plays a vital role. An early treatment with the drug increases its efficiency.

What is the study procedure?
First you will receive an injection into a vein. You will get a drip over eight hours then. We will collect some information about your medical condition. We will send this information to a central office in Nottingham. We will carry out an additional CT brain scan. This scan is like the CT brain scan you had to diagnose your stroke. The additional CT brain scan is important. It allows us to monitor the effect of the drug.
This study is a randomised clinical trial. There are two groups of patients. The patients of group A will get the drug. The patients of group B will get a placebo. You will be randomly assigned to either group A or group B (control group).

Can I ask for more details?
Yes, of course. We will provide more information later. For now, we need to focus on your treatment. Your medical condition is very time sensitive.

How can I give my consent?
Have you understood everything? If so, please fill in the consent form below and sign it.

FORM (complete only where required (marked by *))
Do you want to participate in this study?
Yes, I want to participate in this study.

*Name:
*Signature:
*Date:

Witness name:
Witness signature:
Date:

At this point we cannot provide a detailed linguistic analysis of the modified text document that we propose. The main modifications are that we changed the structure of the text. In its modified version it is an imitation of a dialogue structure and makes use of the common linguistic action pattern QUESTIONING-

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ANSWERING. The questions are formulated from the perspective of the patient. The answers are given from the perspective of the researchers. Many websites use this form of standardisation (frequently asked questions (FAQs)) to avoid providing a customer service and contact possibilities.[11] The modified version of the information sheet and consent form imitates an oral communication situation. One person (the patient) has a lack of knowledge about the situation, i.e. her/his medical condition and why she/he is approached by researchers. The other person (the researcher) can provide information which closes the patient's knowledge gap. This is done by verbalising assertions. While the patient needs to understand what her/his medical condition is and what the study is about, the researcher needs to act ethically by providing sufficient information to the patient to get her/his informed consent. The researcher also has the obligation to make sure that the patient understands the provided information. On this basis the patient can be enrolled in the study. As mentioned before all this is a very time-sensitive issue. Also, it is a complex configuration in which the patient needs to read a written text while she/he is physically participating in a discourse (oral communication situation). From this perspective it also makes sense to modify the text in such a way that it is like a discourse to increase its functionality. Given the discourse situation, the researcher can make sure that the patient understands the provided information. On the other hand, the patient can directly ask for clarification and more detailed information.[12]

4. Conclusion

Law *et al.* (2022) show that using a 2-stage consent with an initial brief consent and information document led to a faster enrolment of patients in the study. The initial consent based on the brief text did not lead to a significant number of patients dropping out when they had to give a full written consent later. A faster patient enrolment can lead to a greater success of the medical treatment. The brief text plays an important role in this context. At the same time, it serves an ethical and legal purpose. It is a highly standardised institutional text.

Using the fog index for determining the readability of such a relevant text is a makeshift solution. It only considers the average sentence length and complexity of words which is conceptualised as the number of syllables they have. Measures such as the fog index are rather quantitative measures. Of course, a text is more than merely a string of words. The complexity of a text, i.e. the difficulty level of its comprehension is not determined by computing the sum of words it contains.

The fog index assumes that a text is appropriate and comprehensible if 13- to 14-year-olds can understand it. Children at this age go to school daily. There they are confronted with a variety of written texts which are specific to the (educational) institution. They build routines in dealing with these texts, they

[11] This reduces the institutional client's agency, i.e. her/his (potential) scope of (linguistic) action.
[12] Both interlocutors can secure their comprehension (Kameyama 2004).

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frequently and regularly read and write them. This does not need to be the case with adults. Factors such as education level, occupation, socio-economic status, etc. play a role regarding reading habits and comprehension levels of adults. To assume that every adult should be capable of reading and understanding texts which are suitable for 13–14-year-old school children does not meet the real linguistic environment and skills of some adult patients. Also, not every adult is experienced in dealing with very specific standardised institutional texts. In addition, it needs to be emphasised that after having a stroke these patients are in a very special and stressful situation. Their main attention is on their condition. They are worried. It cannot be ruled out that their comprehension capacities are (partially and temporarily) impaired due to the stroke so that they cannot (completely) understand the text and what is going on in general. And finally stroke patients are usually older than 13 or 14 years of age. They have different knowledge resources than these children.

Data on the patients' language biographies and linguistic skills needs to be collected and considered. Linguistic research can contribute to a better (scientific) understanding of how texts need to be linguistically designed to be understood in such situations by patients and to serve the purpose(s) for which they are created. Such studies involve real readers (the patients) in authentic communication contexts.

The (functional) linguistic analysis of the text shows that there are several complex linguistic phenomena on the (i) word, (ii) phrase and sentence, and (iii) text level which can potentially cause comprehension difficulties. Many of these phenomena are not considered at all by the fog index. Based on the linguistic analysis we suggest a modified version of the brief patient information sheet and consent form. This modified version makes use of the common linguistic action pattern QUESTIONING-ANSWERING[13] and thereby imitates a discourse, i.e. an oral communication (or: dialogue) situation. An intervention study is needed to find out whether the modified version leads to a better understanding of the text on the side of the patients. In addition, studies are needed to find out how the discussed linguistic phenomena influence the text comprehension of real patients.

Researchers need to take the meaning of the phrase *informed consent* more seriously. This is a matter of research ethics. Giving consent is a personal choice. It should be based on provided information which is understood by the persons giving consent.

The proposed (and applied) text analysis framework can be used as a template for determining the complexity of a specific (institutional) text in reference to the level of text comprehension required of a reader. In any case a text is more than a sequence of words, word groups, and sentences. Its functionality can only be captured and comprehended if supra-sentential text phenomena as well as its embeddedness in institutional communication are systematically considered. This also allows for the unveiling of power relations

[13] This action pattern is functionalised here.

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– such as the interactional establishing of agency – through functional linguistic analysis.

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