

LIVECHART

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The LIVErpool botulinum toxin effects CHART



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Introduction

Developed by Dr Moore of the Walton Centre, NHS Foundation Trust, Liverpool, the LIVECHART has been used clinically for over 20 years in the optimisation of botulinum toxin treatment.

The LIVECHART:

- Is a concise record of the injections given and patient-reported effects of treatment on a single sheet
- Can be used for most indications including dystonia and spasticity
- Provides much of the information needed to quickly understand treatment history and outcomes
- Can give a clear view of a patient's progress over multiple injection cycles when used regularly
- Can improve decisions about the next treatment cycle and overall management strategy
- Is especially valuable when a different clinician has to assess the patient at each visit

The LIVECHART has 6 sections:

Section 1: Treatment details

Diagram* and grid on which the sites of injection, doses and toxin preparation used can be recorded by the clinician.

Section 2: Visual Analogue Score (VAS) table

A weekly VAS table to enable patients to record how well the injection is working.

Section 3: Effects of treatment

A series of questions to clarify the timing of toxin effects and duration of action.

Section 4: Adverse events

A section for patients to report adverse effects.

Section 5 and 6: Likert scale

A 7-point Likert scale for patients to record:

- Overall effect of the most recent injection, from *major deterioration* to *major benefit*
- Comparison with previous injection, from *much worse* to *much better*

First patient visit

Full instructions on how to use the LIVECHART should be given to patients on their first visit, ideally with friend/carer listening.

The following instructions have been designed to help you to cover all key points. Care has been taken to ensure that the verbal instructions are clear but you may wish to adapt them for individual patients.

Hold the LIVECHART the right way up for the patient and use a single pointer to clearly indicate the section you are describing.

Explain to the patient:

"This is a homework sheet so we can tell how well your injections have worked and adjust them correctly next time round."

Section 1

Explain to the patient:

"This top section shows what treatment I have given you. I'll fill it in"

When you complete the muscle selection and dose grid, do fill in the total dose and which preparation you have used. Reproduce this grid in your notes, keeping the same sequence.

Try to establish consistent shorthand and order for the muscles treated to use for all patients. For instance, in cervical dystonia, a roughly 'front to back' sequence descending the grid, i.e. sternomastoid (SM) – splenius capitis (SC) – levator scapulae (LS) – trapezius (T) – semispinalis (SS).

In limb injections, it may be useful to cluster muscles with similar actions, ordering them broadly from proximal to distal, such as biceps (B), brachialis (Brach) and brachioradialis (B'rad) for elbow flexion.

Section 2

Explain to the patient:

"For Question 1, please rate how well your injection is working each week [point to 'WEEK'] by ringing one of the numbers. Write the date in the box [point to the date box]. 100 means no problem, 0 is terrible, as bad as you can imagine [point to each number in turn]."

"Think how your [neck / eye/ face etc] has been over the last week or so and pick a number."

If the patient struggles to choose a number it may help to say:

"Don't worry about being precise, just pick a number."

Do not mark the patient's initial selection straightaway. Wait until you have established a lifetime baseline severity or 'worst ever' point by asking:

"Have you ever been worse than you are now, and what score would you give for that?"

This sequence is important as patients sometimes misunderstand the necessary direction of change for benefit or deterioration. If they consider their current level as being their 'worst ever', ask them to point out a score for being half as bad as they are now.

If the indicated scores are very low, point out that the patient needs to leave room to show any deterioration, and suggest they choose a higher VAS.

When you are satisfied that the patient understands the scale, mark the baseline severity with an arrow above the table and ring the number for their current level to demonstrate the method.

Explain to the patient the likely pattern of VAS scoring over an injection cycle:

"Usually the injections start working in the next few weeks. It can take as long as 3 or 4 weeks but then your score should begin to rise. It may continue to improve over a few more weeks then stay the same for a while. It will then probably begin to wear off. Even if there is no change, please still mark it on the LIVECHART. If your symptoms are no trouble at all, that would be 100. If you get worse, the score would go down."

Demonstrate the idea of the likely curved pattern by waving a pen vaguely over the LIVECHART, but try not to pre-define a particular amplitude or duration in the patient's mind.

Explain to the patient:

"If you forget one week, just fill it in as soon as you remember as it is easy if only a week has passed, but is much harder if you wait a month or more"

Section 3

Explain to the patient:

"You can answer the questions in section 3 usually in order, such as [read out the first one or two questions]."

Section 4

Explain to the patient:

"If there are any side effects please record them in these boxes [indicate the adverse effect boxes]."

For some patients you may need to expand on this, providing appropriate examples.

Section 5

Explain to the patient:

"When you come back to clinic please bring this LIVECHART with you, and you can mark whether there was any benefit or if the treatment made you worse. Leave section 6 for now."

Most patients can complete at least some of these sections. If necessary, a carer, friend or health professional can help or complete the form on their behalf. The LIVECHART works best when the same person fills in the form each week and for every injection cycle.

Giving the injections

While injecting patients you may find the injection diagram and grid of section 1 to be a useful aide-memoire which reduces the risk of errors. This is where establishing consistent shorthand and a pattern/sequence for filling out the grid, both on the sheet and in the notes pays off. You will be much less likely to make a mistake in injection placement.

* The diagram can be changed to that of another body part if necessary

Follow-up visit

Ask the patient straightaway for their LIVECHART.

If your patient does not have their LIVECHART, it may be useful to show mild disappointment and tell them they will need to rely on memory to report their progress. Usually they find this more difficult than they expected and struggling to remember the sequence of events over 3 months reinforces the importance and usefulness of the LIVECHART, encouraging them to complete it next time.

An occasional excuse is that there was no change to record. Point out that this is still useful information to show whether a different dose or pattern of injections works better.

It can be worth getting a new LIVECHART and filling it in retrospectively with the patient to reinforce its importance and to have at least some results for the important first injection cycle. This may also help reassure patients who did not understand how to use the LIVECHART from the previous visit, making them more likely to complete it next time.

If your patient produces their LIVECHART, examine it pointedly to reinforce its importance in improving their treatment. Do not rely absolutely on the LIVECHART, especially at the first follow up visit. Cross-question patients to make sure they have used the LIVECHART correctly and if you detect errors you then have the opportunity to put them right with the patient/scorer watching.

Consistently reviewing and questioning the LIVECHART in order also trains the patients to think logically about their injection cycle to minimise confusion.

Common first-time errors include:

- Scoring *better as a lower* VAS score
- Not using distinctive symbols so scores for separate items get mixed up
- Not clarifying whether timescales recorded for sections 3 and 4 represent days or weeks
- In section 3, using time elapsed since the injection to answer question 3c to 3f rather than just questions 3a and 3b. For example, the patient may indicate the injection has worn off completely 'for' 16 weeks but really mean 'at' 16 weeks, post-injection. Usually an explanation will suffice, but if your patients do this repeatedly, it may be worth changing the wording or switching to elapsed time for all the questions for that patient.
- Missing or adding in weeks, especially if the LIVECHART is filled in retrospectively. You can check this by comparing the results against the actual interval between injections. Incomplete results may not harm but could turn out to be important if there is any question of developing resistance or diminishing benefit duration.
- Mistakenly ringing the wrong Likert score in section 5 e.g. *moderate deterioration* rather than *moderate benefit*. This may be a result of patient just reading the word '*moderate*'. This is easily detected and corrected if you consider it.
- In scoring in section 5, some patients mark their current (end of cycle) state rather than how they were when the injection was working. This discrepancy is usually obvious, easily corrected and the process helps to teach patients about the injection cycle.

Fill in the next LIVECHART, remembering to transfer across the last VAS score and lifetime baseline severity arrow. If there is no recent VAS, establish a new one. This all helps to maintain constant calibration.

At the second treatment session, remember to explain section 6 of the Likert scale:

"At your next visit you can use this line to say whether these injections worked the same or were better or worse than the last ones."

Things to look out for

Some patients become blasé and clearly fill in the whole LIVECHART on the day of the follow-up appointment. It is rarely worth challenging this as these patients are typically the ones who remember quite well anyway.

Some patients have to be guided through the LIVECHART repeatedly, or never get the hang of it. Some decide not to complete it, but may restart if they experience a less effective injection cycle than usual and can be persuaded that using the LIVECHART will help optimise future cycles.

If you anticipate an injection cycle longer than 18 weeks, give the patient a spare LIVECHART or tell them to fill in the VAS monthly not weekly. They will need to remember to fill in the dates.

If a patient forgets to bring a LIVECHART, ask them to send it or bring it next time.

Adapting the LIVECHART

The symptoms selected for VAS rating can be made as specific or broad as seems appropriate. The score can use a pre-defined scale to guide the patient or be left open to their interpretation.

If there are multiple symptoms or body areas treated you can ask the patient to give either a global VAS or to split scores separately, e.g. for pain and posture, or arm and leg. Predefine the scoring symbol or colour for each by writing it on the LIVECHART. Colours are good, but different symbols an advantage for photocopying. However, it may be better to reserve multi-symptom split reporting for subsequent cycles, when you are certain the scorer understands the basic concepts using a single global score.

Your notes

Do not rely on the LIVECHART as your only note-taking. The patient may not bring it back to the next visit. You must record the consultation separately in the notes.

Ensure you record the:

- Interval between injections
- Treatment grid with a consistent pattern matching the LIVECHART
- Time of effect onset
- Weeks since the injections were no longer working well enough
- Adverse effects
- Likert responses

Develop consistent shorthand for your clinic so you can visually scan multiple consultations on one page of the notes. This helps the mental process of comparing patterns, doses and responses over multiple injection cycles. It is much harder if you have to keep leafing through multiple pages. Be careful it is not too obtuse – others may need to understand it. If necessary, have a key.

Another benefit of using the LIVECHART is that if the patient's notes are missing at a consultation, the LIVECHART may save the day.

Basic interpretation

A 'standard' 3 month good treatment response will typically show several phases:

	Typical duration
Initial lag	0-4 weeks
Steadily rising improvement	0-4 weeks
Plateau	2-10 weeks
Wearing off	1-6 weeks
Worn off	0-6 weeks

Many patients have longer or shorter injection cycles and each phase may be short or prolonged.

With the Likert scales (section 5 and 6), you can calibrate the patient's interpretation of the VAS scale against their perception of the degree of benefit.

Every patient is different: some record 5-10% VAS change and report this as a major benefit, others a 90% VAS change for only minor benefit. It is their choice, and they will tend to be consistent over many injection cycles.

Some patients show an initial VAS dip, which may be due to continuing wearing-off of the previous injections before the new ones take effect, or to a period of adverse effects. Occasionally this phenomenon is pronounced or very prolonged, in which case you should consider whether the injections are harming not helping, and the patients are merely recovering back to baseline before the next injections. A safeguard here is to be clear the previous injections are wearing off before re-injecting.

Fluctuating VAS responses or a flatter VAS curve than usual should prompt queries about intercurrent problems.

Sections 3d-f split the core question "How long is it since the injections wore off?" This is often a difficult question for patients to interpret unambiguously.

Does it mean:

- How long since my treatment started to wear off?
- How long since my treatment has not been working well enough?
- How long since my treatment wore off altogether?

Make sure you are clear.

The second question is the crucial one so it may be helpful in the review clinic to ask patients directly:

'How long have the injections not been working well enough'

This provides you with information about important gaps in symptom control.

After a few injection cycles it is often clear the patient has a consistent VAS threshold for 'not working well enough'

Advanced interpretation

The pattern of responses over multiple cycles is easier to assess using the LIVECHART. A steadily diminishing response, with lower amplitude, duration or both, might suggest developing biological resistance to botulinum toxin. A worsening baseline might suggest deteriorating underlying disease. The effects (or not) of changed dose or pattern of injections, or of adding another treatment are clarified, and so on.

Adverse events

If you are trying to decide if a recurring symptom is due to the disease or is an adverse effect, ask the patient to score its severity on the VAS. Adverse effects such as dysphagia should occur as the toxin takes effect and will usually fade after a few weeks. Dystonia-related dysphagia will fade as the toxin starts to work and will recur as the toxin wears off. For consistency, remember that for adverse effects a VAS of 100% is normal and a lower VAS is worse.

Managing uncertain benefits

When there is doubt as to whether toxin injections are effective, the LIVECHART is excellent as a way of recording results in a blinded

N-of-1 crossover trial. If this is likely to be helpful I negotiate with the patient and agree the trial in advance, and perform it double-blind with 2 placebo and 2 active injection cycles (occasionally 1:3). Patients are usually convinced by reviewing their own written responses at the end of the trial.

Scorer consistency

Beware of LIVECHARTs where there has been another scorer taking over part-way. They are likely to use different calibrations, of the VAS especially. Be careful about comparing two LIVECHARTs filled in by different carers. It is also risky to compare VAS scores between individual patients.

Crosschecking

If you doubt the patient's ability to use the LIVECHART, it might help to gain a more objective view of changes through the cycle by asking a relative, friend or carer to fill in a separate, parallel, LIVECHART without colluding with the patient. Comparing the two gives some assessment of the patient's ability. Discussion of any discrepancies may help the patient to use the LIVECHART more effectively. Bear in mind that subjective responses can differ from objective changes, especially for factors such as pain relief.

Visualising the dystonia

A major benefit of having the grid recording injection patterns and the VAS outcomes on one page is the ability to match the pattern to its effect, allowing visual comparison over multiple injection cycles.

If you fill in the grid using a consistent sequence of muscles, with practice you can often reconstruct in your mind the directions of dystonic movement at that time and the relative importance of different features of the dystonia from the grid pattern and doses used. This works better if you ensure a matching sequence is used in your notes.

For instance, a patient with cervical dystonia involving head rotation to the right, tilt left and left shoulder elevation might receive a pattern of:

	R	L
SM		150
SC	150	
LS		100
T		100

TOTAL: 500 Dysport

When the next injections are due, if the previous injection pattern 'matches' the current dystonia, repeating the injection pattern is likely to reproduce the effect. If there were adverse effects or some element of the dystonia was not corrected or was aggravated, it is easier to work out what modifications are needed to the injection pattern.

You can also recognise residual toxin effects more readily. Commonly, a patient treated as above may still have left shoulder droop at the end of the injection cycle, giving the misleading impression of an elevated dystonic right shoulder. You will be prompted to check with the patient which shoulder pulls upwards or is painful.

If the current dystonia does not match the pattern of injections you should explore the reason. Perhaps:

- The patient's dystonia has changed
- You used a suboptimal dose or pattern of injections
- The previous injections are still 'contaminating' the dystonia, as per the example above with a droopy left shoulder
- There is a 'pseudodystonia' or 'counter-dystonic' posture. For example, the patient above with cervical dystonia and primary right rotation may subdue it by holding the head turned slightly left, especially if there is still some residual toxin effect. You will be able to easily see that this counter-dystonic posture does not match the injection pattern used and avoid the mistake of injecting the right SM.

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Quantifying overall benefit with AUC analysis

Many studies of botulinum toxin primarily report changes in severity scores at peak effect and a measure of benefit duration such as return to baseline. Each of these are helpful but even together they do not represent a convincing measure of overall benefit as they give no indication of the duration of acceptable symptom control.

An Area-Under-the-Curve (AUC) analysis of the VAS scores intuitively measures the overall subjective benefit in an injection cycle and is a good way to compare subsequent cycles. Arguably, the subjective benefit is more important than any objective measure as botulinum toxin is a symptomatic treatment. However, this is not a fully validated measure as yet, though AUC analysis of VAS scores have been used in at least one study.¹ Note that AUC analysis is less suitable for comparing one patient with another.

There are several options for establishing a 'baseline' including:

- 0%
- Patient's worst ever score
- Score at start of first or current injection cycle
- A VAS score taken after a number of injection cycles which the patient feels represents a 'good enough' effect. This can also be helpful in deciding optimal injection intervals

Reference:

1) Moore A, Rog D, Bulloch R, Collins D. Randomised, open label, crossover comparator trial of doctor and nurse-given botulinum toxin injections. *Mov Disord* 2002; 17(S5):S240.