National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MTG19 –**The geko device for reducing the risk of venous thromboembolism**

**Consultation C**ommentstable

There were 17 consultation comments from 5 consultees (3 NHS professionals, 1 manufacturer and 1 other). The comments are reproduced in full.

Table 1

| Com. no. | Sec. no. | Comments | Response |
| --- | --- | --- | --- |
|  | 1 | As there has been no substantial change to the evidence I agree that the guidance should be transferred to the static guidance list. | Thank you for your comment.  |
| 1. 4
 | 1 | Firstkind welcome the recommendation to place MTG19 on the static guidance list after this review is complete. This gives Firstkind the confidence to maintain a market focus that targets those hospitalised patients who are currently unable to be prescribed pharmacological and mechanical forms of VTE prophylaxis. Firstkind believe that MTG19 supports the clinical objective of providing hospitals with further capability of prescribing VTE prophylaxis to all hospitalised patients 100% of the time. | Thank you for your comment.  |
|  | 1 | Firstkind understand that the 2nd paragraph of the consultation recommendation will result in an amendment to the current MTG19 guidance web landing page with “explanatory text” and a “signposting” about the CG92 recommendation for stroke. Further, this presumably will state that because no RCT evidence for NMES (as a generic) was found in the CG92.1 review then NMES (as a generic) is not recommended in stroke patients. Firstkind make this assumption because Section 4 of this consultation suggests that Appendix 1 describes these signposting/text options but doesn’t appear to do so?This CG92 position in respect to NMES and stroke has created confusion and contradiction when aligned with the MTG19 position for the specific geko TM device. MTG19 supported the use of the geko TM device because the committee agreed that its mode of action and resulting blood flow/anti-stasis impact was superior to no VTE prophylaxis in all hospitalised patients. There is no evidence that has since emerged that could possibly dilute that position for all patient groups, including stroke. Indeed new evidence has since emerged that would further support the original committee’s decision.The market understands the difference between CG and MTG guidance and the different levels of evidence required to gain a positive recommendation in each. The CG92.1 review for reasons that continue to be unclear decided to take the unusual step of highlighting in final CG92 guidance that the generic NMES technology was not recommended for stroke. When NICE created the original VTE guideline CG46 in 2007, NMES was rightly removed at consultation stage because of the same lack of RCT evidence in any population. This policy was repeated in the 2010 revision (named CG92) where again NMES was not considered because of a lack of RCT evidence. In both 2007 and 2010 this negative RCT finding in respect to NMES was not translated to a non-recommendation statement on a patient group basis in final guidance, yet the CG92.1 review has created significant market problems by doing so.Firstkind believe there is a meaningful difference here in how insufficient RCT NMES evidence has been translated by NICE into the final CG92 stroke guidance and it is this inconsistency that has undermined MTG19 and the unique properties and patient benefits attributed to the geko TM device, benefits that should serve stroke patients when IPC is contraindicated or impractical as MTG19 always intended. On the basis that there no new evidence or no new safety concerns that would undermine the current MTG19 recommendation and the use of the geko TM device in stroke and as such there is no basis for amending MTG19 to isolate stroke patients from what is a highly useful generic guidance for unmet need. Further, from a patient perspective, and in light of the above facts, it would seem incoherent for NHS England to regress and effectively offer no VTE prophylaxis to stroke patients when other modalities are contraindicated or impractical. Today, the NHS England is using and intends to use the geko TM device in stroke patients in the way that MTG19 currently recommends and to retreat from this clinical progress would surely alarm clinicians and patient groups alike. Given the factual status of the above comments, Firstkind ask that that this signposting or text insertion isn’t made because it is surely a retrograde step at all levels. | Thank you for your comment. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>. NICE signposts relevant related guidance which can impact on a care pathway. CG92 is currently being updated and prospective stakeholders should register on the NICE website Appendix 1 of the review proposal describes the options after guidance has been reviewed; it does not include text used to signpost users to related NICE guidance.  |
|  | 1.1 and 1.2 in recommendation 3 | This area of recommendation is supportive of using the Geko for stroke patient when other means of VTE prophylaxis are contraindicated | Thank you for your comment.  |
|  | 3 | Firstkind understand that the 2nd paragraph of the consultation recommendation in section 1 will result in a signposting/text insertion (which Firstkind would prefer not to happen as explained above).If it is intended that an amendment is also made to the current MTG19 guidance recommendation which is scribed in section 3 (which isn’t clear from the consultation proposal), then Firstkind would use the same argumentation outlined in 2 above and ask that the current recommendations remain unchanged. The market values the generic nature of the current MTG19 recommendations. It facilitates the objective of giving all hospitalised patients DVT prophylaxis 100% of the time. However, if this consultation is seeking to remove the generic simplicity of MTG19 which currently recommends the geko TM device for all hospital patients and isolate stroke patients then Firstkind believe, for the reasons given above, that this would be a regressive, confusing and based on the available evidence an unjustified development. | Thank you for your comment. There are no changes to the recommendations reproduced in section 3. The signposting will use standard text which helps users find related guidance. |
|  | 4 | This section suggests that Appendix 1 contains a list of signposting options/text that would appear on the MTG19 landing page but it doesn’t appear to do so? | Thank you for your comment. Appendix 1 contains the options for medical technology reviews as ascribed in the addendum (see link). <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/MTEP-Interim-addendum-guidance-review.pdf>  |
|  | 6.1 | The section refers to gekoTM plus. This is an error, the second generation device currently sold to NHS England is named the geko TM device T-2 which as described in the information request update which was submitted by Firstkind, as requested by NICE, in January 2016 | Thank you for your comment. This has now been amended.  |
|  | 6.2 clinical practice | The narrative is confusing as initially it stated that Geko can only be offered to stroke patients only in the context of research. The last paragraph is in line with using the Geko when other means are contraindicated. This is also in line with the final summary of the recommendation. It is of concern if NICE decision is to deny the stroke patients who are one of of the highest VTE risk groups, prophylaxis with GEKO when other modalities are contraindicated. This is despite the fact that NICE in the recommendation that GEKO got enough evidence to support it as a robust VTE propyhlaxis device | Thank you for your comment. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>. CG92 is currently being updated; any issues relating to the recommendations of CG92 can be submitted as part of this process.  |
|  | 6.2 | Irrespective of the new CLOTS 3 evidence, Firstkind believe that there will always be stroke patients who cannot be compressed or cannot tolerate IPC. Indeed CLOTS 3 reported “significant increase in skin necrosis” in patients who were prescribed IPC. Anecdotally Firstkind have been told that stroke patient compliance with IPC is as low as 30%. It is these very stroke patients who would then fall-back on the current MTG19 recommendation and could be prescribed the geko TM device. If this option is removed, it is inconceivable that stroke patients who are at very high risk of VTE should be left with no mechanical compression option and it was precisely for these reasons that MTG19 was originally devised and it is for these reasons that NHS England plan to and is using the geko TM devicein stroke patients.While the update to CG92 considered mechanical prophylaxis effect and associated health economics in stroke patients, Firstkind do not feel that this analysis is relevant to the current MTG19 review. The cost-effectiveness analysis conducted by Dennis et al. 2015 that has been referenced in CG92 is a cost-utility analysis whereas the requirements for the MTG19 process require a cost-consequence analysis. As such, a significant portion of the uncertainty in this analysis, relating to quality of life, is irrelevant to the cost-consequence analysis required for MTG19. The scale of the uncertainty in Dennis et al. appears to be the main reason for excluding stroke patients from MTG19 however, excluding the uncertainty associated with quality of life would mean that the cost-consequence analysis, and associated assessment of uncertainty, previously provided by Firstkind for MTG19 would still be relevant. Further to this, the Dennis et al. cost-effectiveness study does not meet the NICE reference case, as specified in the NICE Guide to the methods of technology appraisal 2013. Specifically the analysis fails to consider an appropriate time-horizon. The analysis is limited to the trial time-horizon of six months and therefore fails to capture costs and impact on quality of life associated with some of the consequences of the DVT. These long-term consequences were considered in the analysis provided by Firstkind for MTG19, were accepted by the committee and as such Firstkind feel it is still appropriate. In terms of specific health economic considerations, section 6.2 suggests that the MTG19 cost modelling is “subject to considerable uncertainty for patients with stroke”. It should be stressed that the committee who reviewed MTG19 didn’t think that this was the case. However, Firstkind have re-examined the health economic model in respect to stroke and have modelled the CLOTS3 outcomes, this is summarised below. The original MTG19 cost consequence analysis is updated below to incorporate the CLOTS3 data: * Reducing the baseline risk of deep vein thrombosis (DVT) with no prophylaxis from 29% for a generic population (as per MTG19) to 21% as seen in the control arm of CLOTS3
* Increasing the proportion of those DVT that are symptomatic from 20% in a generic population to 30% as per CLOTS3

When the above is modelled as per MTG19 the following economical outcomes result for stroke patients: * If we assume **6 days** of treatment and a relative risk **(RR) of 0.39**, as per the MTG19 analysis, the use of the geko TM device results **in savings of approximately £210 per patient compared to no prophylaxis**

.* If we increase the duration of administration of gekoTM device from 6 days **to 12 days**, the mean duration of IPC use in CLOTS3, and a **RR of 0.39** then the geko TM device is associated with a **cost saving of approximately £60 per patient compared to no prophylaxis**.
* If we assume that geko TM device is equivalent to IPC in stroke and amend the RR from the 0.39, used in MTG19, **to 0.76**, as reported in CLOTS3, and assume a duration of administration of the geko TM device of **6 days**, the use of **geko is cost-neutral** **compared to no prophylaxis** (i.e. the incremental cost of providing geko is offset by the cost savings achieved by preventing DVTs)
* If we assume a **RR of 0.76** as reported in CLOTS3 and increase the duration of administration to **12 days** the geko TM device is associated with an **incremental cost of approximately £150 per patient compared to no prophylaxis.**

The original cost-consequence analysis considered a cohort of patients at risk, including stroke patients, and was shown to be cost saving under all sensitivity analysis scenarios. While the CLOTS3 study shows that mechanical methods of prophylaxis reduce the risks of DVT, Firstkind do not feel that this would fundamentally change the analysis previously conducted for MTG19. Since no new appropriate evidence for NMES has been identified Firskind would request that the current MTG19 recommendations remain unchanged.  In conclusion Firstkind remain convinced that the economic benefit of using the geko TM device in patients whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated, which would include stroke patients, as calculated via the required MTG19 cost-consequence model, remains compelling.  | Thank you for your comment. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>.  |
|  | 6.4 | Firstkind have notified NICE that some confidential new evidence was submitted as part of this consultation process that should have been highlighted in this section and in Appendix 2.This study by Nicolaides and Griffin examines the effect of the geko TM device on the blood flow within the deep veins of the calf, namely the gastrocnemius vein, the popliteal vein, peroneal vein and the posterior tibial vein and makes reference to the soleal vein. This study has demonstrated that the geko TM device enhances blood flow and velocity in the deep veins of the calf which are clinically significant in terms of early thrombus formation. It is the first time that a compression device for VTE prophylaxis (i.e. static compression such as T.E.D or dynamic compression such as IPC) has been shown to deliver this deep vein effect and this new data is strongly aligned to MTG19. Firstkind believes that this evidence substantiates MTG19 and supports the use of the geko TM device in all patients, including stroke patients who have no other VTE prophylactic option .This data can be viewed here  <http://www.gekodevices.com/en-uk/geko-video-dvt-prevention-blood-clot-prevention-/recent-videos/deep-vein-study/> | Thank you for your comment. This study has now been added to the recent and ongoing studies table in appendix 2.  |
|  | 7 | Firstkind are confused by this section and it seems some text is also missing? This section says that CG92 has a stroke recommendation that should be followed but then also says that MTG19 can be used for stroke when other methods are contraindicated.Firstkind believe that this confusion began when CG addendum 92.1 was published and our commentary under section 2 refers. Finally this section refers to evidence collected in the CG 92.1 review which presumably justifies its NMES conclusion. The following is taken from the 92.1 review:*“…no new evidence on foot impulse devices (FID) or neuromuscular electrical stimulation (NMES) devices that met the review protocol inclusion criteria despite pre-existing guidance (based on the previous GDG’s opinion only)”.**In the absence of new evidence, the Committee agreed that these devices should also not be recommended for VTE prevention in hospitalised stroke patients for the following reasons:**·        One study that used a form of NMES in acute stroke patients (Pambianco et al. 1995 was reviewed in the original CG92 guidance; data was extracted but not included in this update  because the reported outcomes did not meet the review inclusion criteria - see Evidence Table in Appendix H [p.62/3] for details). The NMES treatment arm in the Pambianco (1995) study was discontinued after 6/8 patients withdrew due to discomfort and blistering. The Committee therefore do not feel a research recommendation is warranted for NMES devices for VTE prevention in this population* Firstkind stress that the NMES technology used in Pambianco et al. 1995 is completely different to that of the geko TM device and completely removes the issues associated with discomfort and blistering. This issue and references such as Pambianco (1995)were debated at length in the MTG19 committee and resolved as part of the positive recommendation which the geko TM device duly received.As such Firstkind believe it is counter-intuitive to prohibit the use of NMES in stroke patients because there is no new evidence for NMES specific to this subgroup when the previous evidence used in MTG19 was indeed sufficient to warrant gekoTM use in stroke patients who have no other VTE prophylaxis option available to them.The above further supports the Firstkind position that MTG19 remains a generic fall-back position for all patients for whom current methods of DVT prophylaxis are unsuitable, including stroke patients. | Thank you for your comment. The relevant sentences have been amended. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>.  |
|  | 7 | First sentence is incomplete…Paragraph is contradictory and doesn’t read well. Refers to CG92 recommendations for other mechanical devices for stroke, then refers to MTG19 population which ‘includes, but is not limited to some people who have had a stroke’ . Confusing and needs clarification  | Thank you for your comment. The first sentence has been amended. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>.  |
|  | 8 | We are using the geko device in patients who have contraindications to prophylactic anticoagulation and to mechanical compression devices. an option for the device in included in our VTE proforma. Use of the device has been through clinical governance and agreed for the above patient group. With patients at high risk of thrombosis it is important to have alternatives if the standard evidence-based methodology is contraindicated, impracticable, or not accepted by the patient.  | Thank you for your comment.  |
|  | General | We are using GEKO devices on patients who have contraindication to wearing IPCCWe have gone through our local governance to use this device where IPCC is contraindicated. | Thank you for your comment.  |
|  | Appendix 1 | This doesn’t appear to cross reference with section 4 “see Appendix1 for explanation of [signposting] options” | Thank you for your comment. Please refer to the response to comment 3 (final paragraph). |
|  | Appendix 2 | This doesn’t reference the new evidence of Nicolaides and Griffin as submitted by Firstkind during this process. | Thank you for your comment. The study has been added.  |
|  | Recommendations | Currently as it stands, MTG19 offers an alternative prophylaxis treatment for those who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods are unsuitable, impractical or contraindicated. Within the review proposal consultation document, it is accepted that GEKO continues as an effective prophylaxis option.AntiCoagulation Europe (ACE) notes the partial review undertaken within CG 92 and it’s reference to 1.3.1 which states not to offer immobile stroke patients foot impulse devices or neuromuscular electrical stimulation devices for VTE prophylaxis unless in the context of research. IN 1.3.2, recommends that intermittent pneumatic compression(IPC) can be considered for stroke patients.Whilst acknowledging the need to align any related update to relevant NICE guidelines, we strongly suggest that any linking or explanatory note clearly states that whilst CG92 does not recommended as a routine prophylaxis for stroke patients, GEKO could still be considered should there be a unmet need due to all other pharmacological/mechanical options not being suitable with an immobile patient being at heightened risk of VTE post stroke or any other medical situation. This is of particular importance for individuals who are deemed unsuitable for IPC but still require safe and effective VTE risk reduction and who may be restricted in access and choice. We would also suggest that the term ‘research’ is clearly defined for patient understanding and transparency. | Thank you for your comment. Medical technology guidance and clinical guidelines rely on different methodologies as detailed in <https://www.nice.org.uk/article/pmg6/chapter/1%20introduction> and <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-medical-technologies/Medical-technologies-evaluation-programme-methods-guide.pdf>.  |

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