

# Blood Glucose Test Strips Review of Products

By MKCCG Medicines Management Team &  
Diabetes Specialist Nurses

# Aims of BGTS Products Review

- Rationalise the choice of strips prescribed locally
  - Accuracy
  - Safety
  - Cost-effective use
- Clear and transparent process to obtain final formulary choices
- Not intended to deny access to BGTS
- Cost cutting is not the sole or top priority
- Project Team

# The Greater Manchester Medicines Management Group

- = GPs, pharmacists & other key health professionals
- Formally accountable to Greater Manchester collaboration of 12 x CCGs, LAT & local NHS providers
- Work plan facilitated & supported by the Regional D&T Centre in Newcastle & the GMCSU

# Self-monitoring of blood glucose (SMBG)

- Essential part of the management of diabetes for some patients
- Excessive testing can negatively impact quality of life
- MK is the 3<sup>rd</sup> highest CCG on BGTS spend
- In MK 2013: >12,000 patients over 17yrs with diabetes
- MK 2014-15 total spend on BGTS >£888K
- (£586K on 1<sup>st</sup> line oral hypoglycaemic agents)
- BGTS 9% increase in cost locally cw 4% increase nationally

# Regulation of medical devices

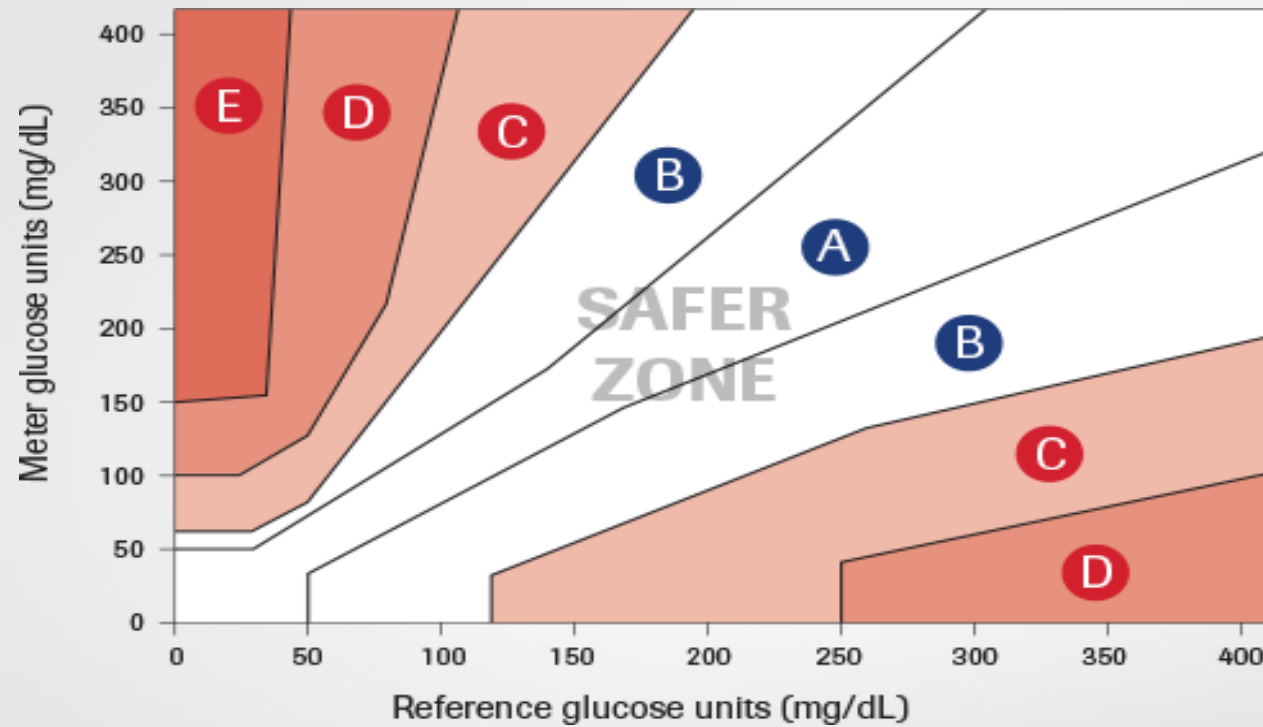
- Jan 15: 58 varieties of BGTS funded within the NHS
- Price range: £6.99-£16.30 for 50 strips
- BGTS & meters are medical devices not medicines
- Require a “CE” (Conformit e Europ ene) mark
- Awarded by Notified Bodies (NBs) who charge a fee
- Critics say:
  - wide variation in the quality of NBs
  - Manufacturers can target those likely to give rapid approval

# International Organisation for Standardisation (ISO)

	ISO 15197: 2003	ISO 15197:2013
Higher level accuracy	>4.2mmol/l +/- 20%	>5.5mmol/l +/- 15%
Lower level accuracy	<4.2mmol/l +/- 0.83mmol/l	<5.5mmol/l +/- 0.83mmol/l
Number of lots	1	3
Results in zone A/B of Clarke Error Grid	n/a	99%

Compliance mandatory from 2016

# Error Grid



- A** No effect on clinical action
- B** Altered clinical action—little or no effect on clinical outcome
- C** Altered clinical action—likely to affect clinical outcome
- D** Altered clinical action—could have significant medical risk
- E** Altered clinical action—could have dangerous consequences

# ISO 15197:2013 Update – also includes.....

- Evaluation of Instructions of Use
- Influence quantities of interfering substances, for example:
  - Commonly used medications
  - Haematocrit (Hct) levels:
    - High Hct eg respiratory conditions - can give falsely low BG readings
    - Low Hct eg pregnancy - can give falsely high BG readings
- The 2013 standard was an essential consideration for MK Formulary



# The Process – based on the Manchester Project

- All BGTS in Jan 15 Drug Tariff assessed & scored
- Stage 1: A review of existing BGTS guidance using the internet
- Stage 2: A review of the currently available manufacturers and independent accuracy evidence (for compliance to ISO 15197:2013)
- Stage 3: A review of the acquisition cost of BGTS
- Stage 4: A review of features & available support offered to patients
- MK – Stage 5: A Patient Panel Review of selected meters

# Essential Criteria: Pass or Fail

- ✓ Free meters to NHS locations
- ✓ Free replacement batteries, log books, lancing pens
- ✓ Technical support provided via Freephone number (not answering machine)
- ✓ Free support material & meter training for all HCPs
- ✓ Free internal control solution
- ✓ Measures only mmol/L units & cannot be changed
- ✓ Provides plasma-calibrated meter readings
- ✓ Hct range between 30-60% (or more)
- ✓ Measurement range between 1.1-33.3mmol/L (or more)
- ✓ Unable to delete readings from memory
- ✓ No calibration or coding required
- ✓ Expiry date of BGTS – min 6 months from opening

## Non-essential criteria (but provides added value): Scored 0-1 based on project panel decisions

- ✓ Guarantee stability of pricing and available BGTS and meters.
- ✓ Starter meter pack available which includes BGTS and lancets.
- ✓ Sample under-fill detection.
- ✓ Able to apply more blood to the same test strip; if under-fill.
- ✓ Capillary fill function.
- ✓ Small sample size required ( $\leq 0.5\mu\text{l}$ ).
- ✓ Measurement time ( $\leq 5$  seconds).
- ✓ Sufficient memory capacity as per project group expectations.
- ✓ Meter set-up is not required (e.g. date and time). However minor adjustment maybe required in BST/battery changes.
- ✓ The manufacturer can provide material and deliver training to patients and carers free of charge
- ✓ Manufacturers to provide records and evaluation of all training to all recipients and highlight learning outcomes achieved and any areas of concerns.
- ✓ The manufacturer supports any promotion of local guidelines for SMBG.
- ✓ Allow electronic download to personal computers and clinical systems.
- ✓ The manufacturer has alternative meters that may support other patient cohorts e.g. measures ketones, supports visually impaired, dexterity issues, gestational diabetes, paediatrics, insulin pump users.
- ✓ Manufacturer provides information of their MHRA product recall process and actions to be taken.
- ✓ Free independent external quality assurance for healthcare professionals in GP practices and insulin users who self-monitors blood glucose.

# The Patient Panel

- Eight meters assessed
- Each meter was evaluated by four patients
- Questionnaire:
  - Ease of following the instruction booklet
  - Use of meter
  - Finger pricking device
  - Criteria for reagent strips
- Rating 1-5 & comments

# Results

- Scoring based on CCG Procurement of services, 60% quality & 40% cost
- Results included impact of Patient Panel scoring

		Accu- chek Active	Care Sens N	WaveSense Jazz	GlucoMen Areo	Contour Next	TEE2	Accu- chek Aviva	Accu- chek Mobile
<b>Patient score</b>		75.6	70.6	77.5	73.1	99.3	80.6	90.6	96.8
<b>20%</b>		15.12	14.12	15.5	14.62	19.86	16.12	18.12	19.36
<b>Evaluation score</b>		87.5	93.7	81.25	93.7	93.7	93.7	81.25	87.5
<b>40%</b>		35.00	37.48	32.50	37.48	37.48	37.48	32.50	35
<b>Total Quality</b>		50.12	51.6	48.00	52.1	57.34	53.6	50.62	54.36
<b>Cost scores</b>		77.9	60.8	78.5	77.9	51.5	100	49.3	48.6
<b>40%</b>		31.16	24.32	31.4	31.16	20.6	40	19.72	19.44
<b>Total Score</b>		81.28	75.92	79.40	83.26	77.94	93.6	70.34	73.80

# Final Recommendations for MK Formulary

- First Tier – For general use**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Accu-chek Active	Roche	£9.95
GlucoMen Areo	Menarini Diagnostics	£9.95
WaveSense Jazz & Jazz Duo	Agamatrix	£9.87 & £9.95
TEE2 (for non-insulin users)*	Spirit Healthcare	£7.75

- Second Tier – For those patients who have found First Tier choices unacceptable**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Contour Next	Bayer	£15.04
CareSens N	Spirit Healthcare	£12.75
Accu-chek Aviva	Roche	£15.79

- Third Tier – For use in special circumstances eg HGV Drivers or other occupational risk grps**

Blood Glucose Test Strip	Manufacturer	Cost per 50 strips
Accu-chek Mobile	Roche	£16.09

# Reviewing & changing BG Meters & strips

- New patients: start on First Tier formulary options  
(- meet the ISO 15197:2013 accuracy standards & also the most cost-effective)
- Suitable existing patients: review & change to one of approved options
- Surgeries can contact manufacturers & obtain supplies free of charge

# Conclusion

- Inaccurate SMBG readings can potentially adversely impact clinical decision making & outcomes
- The more stringent ISO:15197:2013 standard enhances patient safety by improving accuracy
- Although several variables (eg user technique) are known to affect accuracy of results, controllable variables may be reduced by using accurate & evidence-based SMBG systems with minimal lot-to-lot variations
- This review offers formulary options that have greater and more robust evidence confirming compliance to ISO:15197:2013 accuracy standards, as well as offering quality & cost-effective products