Introduction to Newcastle's Type 2 Diabetes Low Calorie Diet Programme

TITO

13th July, 2022

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Newcastle's Type 2 diabetes low calorie diet programme

- Vision for Newcastle
- Collaborative Newcastle
- CCG/Public Health (inequalities) funding for 2 year pilot
- Capacity: ~250 people

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Background: Diabetes remission

- Type 2 remission with low calorie diets started with Newcastle University research (2011)
- Definition of remission: HbA1c < 48 on no glucose lowering medications (2 x HbA1c at least 3 months apart)
- Main principles of remission:
  - Requires 10-15% weight loss
  - More likely with short duration T2DM (up to 6 years)
  - Genetic susceptibility remains: Weight regain = loss of remission. Ongoing T2DM reviews required
- Programmes now established in routine NHS practice

e.g. NHS England pilots

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Key eligibility criteria

- Age 18-65y
- Type 2 diabetes diagnosis ≤ 6 years
- BMI
  - ≥ 27kg/m^2 people from White ethnic groups
  - ≥ 25kg/m^2 people from Black, Asian & other ethnic groups
- HbA1c (taken within last 12m). Repeat if likely to have changed significantly
  - 43-87mmol/mol if on glucose-lowering medication
  - 48-87mmol/mol on no glucose-lowering medication
- Must have attended for monitoring and diabetes review when last invited (including retinal screening)
- **Must commit to ongoing attendance at annual diabetes reviews, even if remission achieved**

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Exclusions

- Current insulin use
- Pregnant or planning pregnancy within next 6 months
- Currently breastfeeding
- One or more significant comorbidities
  - Active cancer
  - Heart attack or stroke in last 6 months
  - Severe heart failure (NYHA grade 3 or 4)
  - Severe renal impairment (most recent eGFR<30mls/min/1.73m^2)
  - Active liver disease (not including NAFLD)
  - Active substance use disorder
  - Active eating disorder
  - Porphyria
  - Known proliferative retinopathy that has not been treated
- Weight loss >5% in last 6 months or currently on a weight management programme
- Undergone or awaiting bariatric surgery (unless prepared to come off waiting list)
- **Health professional assessment as unable to understand/meet demands or monitoring requirements of programme**

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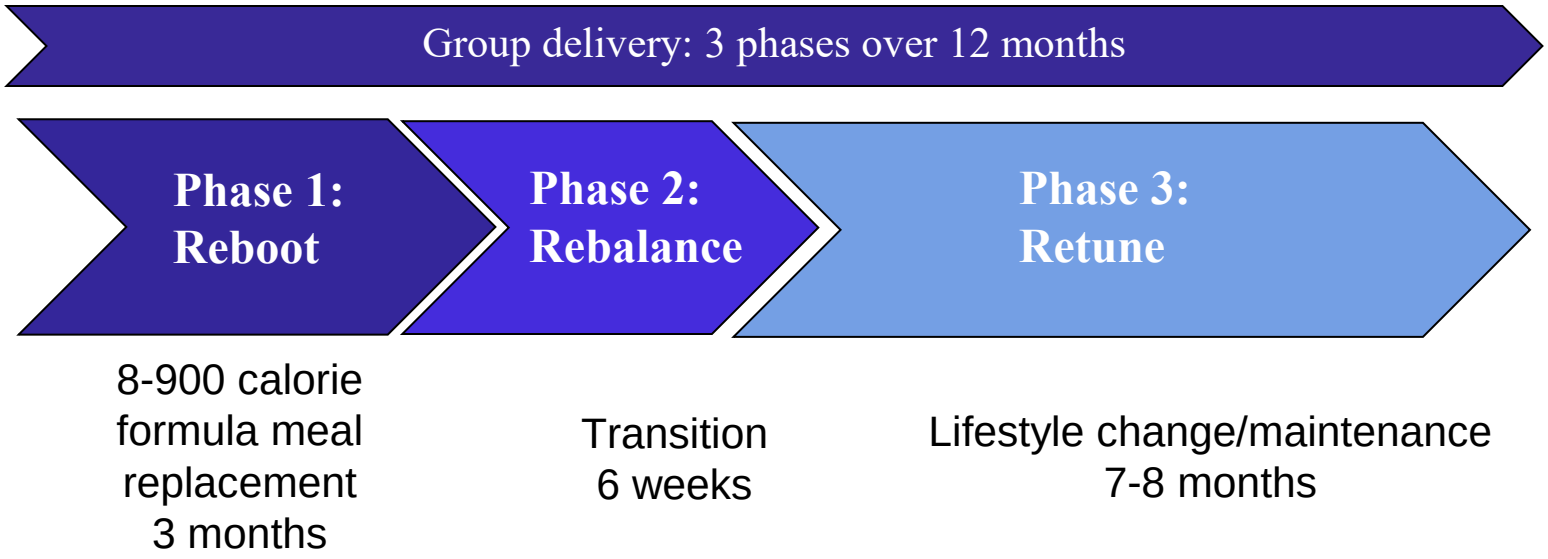
Momenta Newcastle DRP

- 12 month behavioural intervention
- Three phases, all equally important



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NHS Low Calorie Diet Programme
Momenta participant journey

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The participant experience

- Not just “soups and shakes”
- >20 hours of structured group education and support
- 10-15 people / group
- Transferable skills
- Activity support: EXi app
- Positive results so far
  - Weight loss
  - Meds reduction
  - Remission
  - Inequalities

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Participant resources

- Starter booklet
  - Focus on TDR products
- Product Voucher codes
  - 3 x Phase 1, 1 x Phase 2, 1 x Reset
  - Includes free delivery

- Workbook
  - Session overview
  - Content & explanations
  - Activities and quizzes
  - Goals and targets
  - Backup information
  - Safety information

- Trackers e.g. weight, activity, behaviours, specifics

- Online recipe book

- Wallet card
- Pedometer
- EXi app

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Meal replacement products

- No cost to participants
- Wide choice of products (flavours, textures, vegan options)
- Participants order directly (voucher codes provided, support available)
- Free delivery to home / office
- Includes 12-week TDR, transition & 1 weight reset plan if required

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Participant comments in each phase

“I can’t use any terms to express how good I feel”

Rudolf
20kg (20%) weight loss
at end of Phase 1

“It has re-ignited a passion for cooking”

Faraza
18.2kg (23%) weight loss
at end of Phase 2

“I’m smashing it – clocking up at least 15,000 steps every day”

Michelle
14.6kg (15%) weight loss
Midway through Phase 3

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NHS LCD in Birmingham & Solihull

- Virtual groups only – due to Covid
- ~300 starters from ~90 practices on 24 programmes:
  - Uptake: ~90% of referred patients have an Individual Assessment and ~90% of these start the programme
  - Retention and attendance ~80%
  - Average Phase 1 weight loss ~10%,maintained into Phase 3
  - Maximum weight loss: 40% x 2 participants (58kg, 63kg)
  - Health inequalities: Encouraging early indicators
    - Referrals: >50% BAME, >50% lowest IMD quintile
  - 1 x Urdu group
- **Referrals are key!**

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The Newcastle Difference

- Newcastle: ‘Home’ of Type 2 Diabetes Remission
- The ‘Newcastle difference’
  - Choice of
    a. Total Diet Replacement (shakes plus fibre supplement)
    b. ‘Newcastle Diet’ (shakes plus low-starch vegetables)
  - Both virtual (zoom) and in-person (community venues) group delivery options
  - Physical activity and social prescribing support during maintenance

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Programmes starting shortly

- Referrals starting to come in now
- First virtual programme planned for 16th August 7pm then 1-2 per month
  - Depends on participant numbers and demand
- In-person venues being assessed, including:
  - FAR Community Centre, The Beacon, Trinity Centre, Byker and Newcastle Central Community Fire Stations, Byker Sands Centre, Cowgate Centre, Fawdown Children's Centre, Skylight 1, Healthwork's Lemington centre, Leisure centres
  - Other suggestions welcome…

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GP Practice & Provider responsibilities

- Referrals for virtual and in-person programmes can be ad hoc or from ‘clusters’ of practices, ideally ‘clusters’ for in-person

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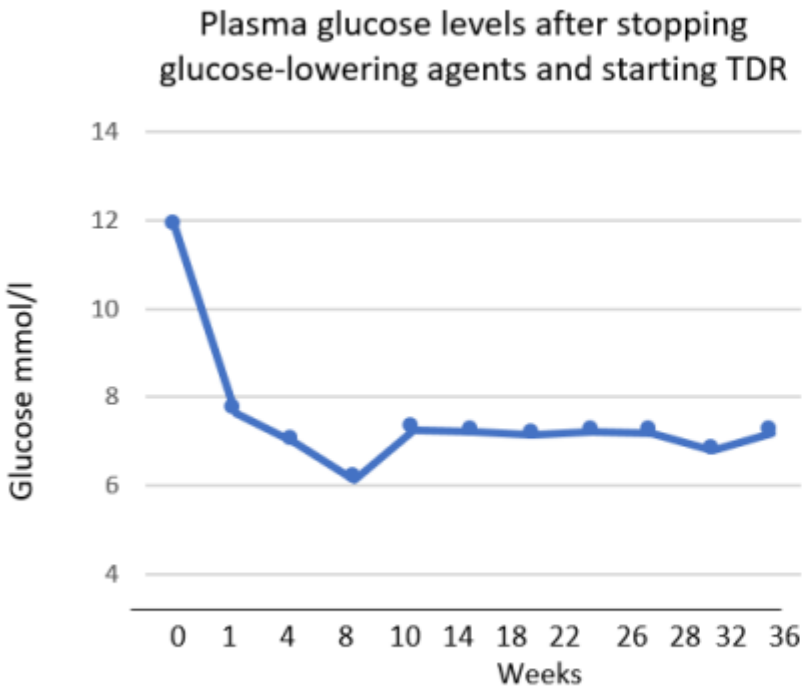
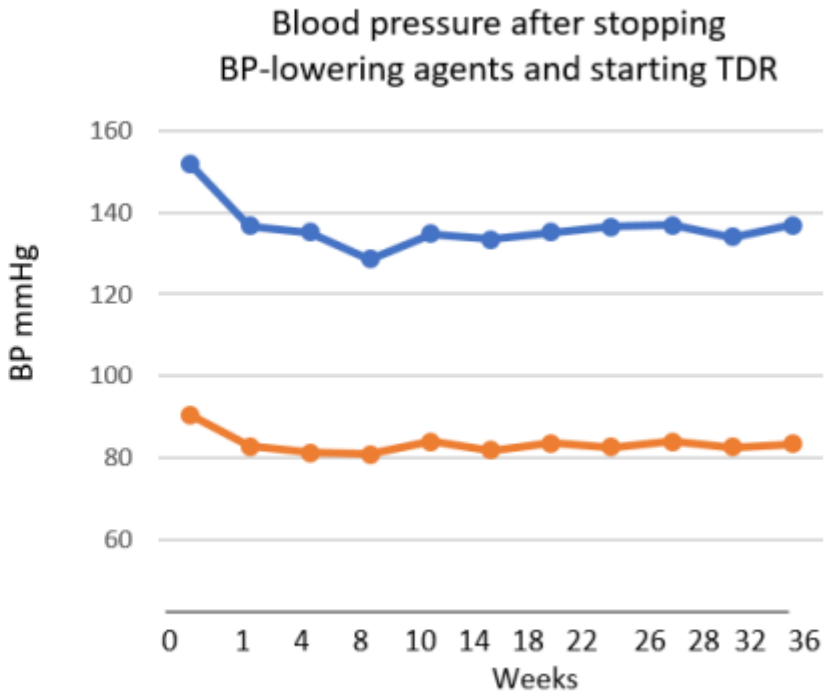
Medication adjustments

- DiRECT Study: all glucose lowering and BP lowering agents were stopped on day 1 of the formula diet
- It is recognised that instructing patients to stop glucose-lowering agents and BP-lowering agents on the first day of a formula diet may seem unusual to practitioners less familiar with the intervention

Medication adjustments rationale





Data from Counterbalance study (informed DiRECT)

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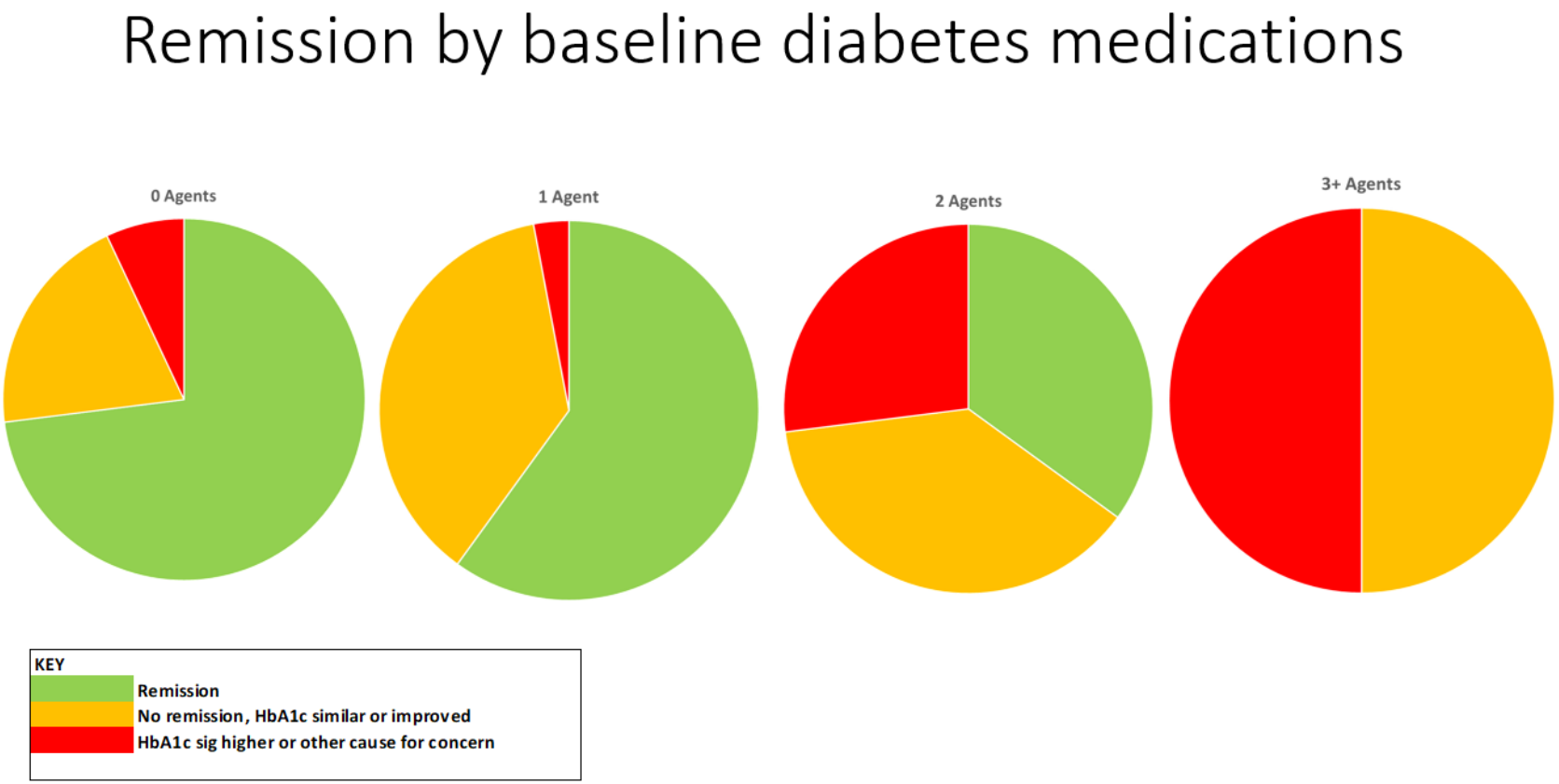
Medication adjustments rationale: BG

Data from DiRECT



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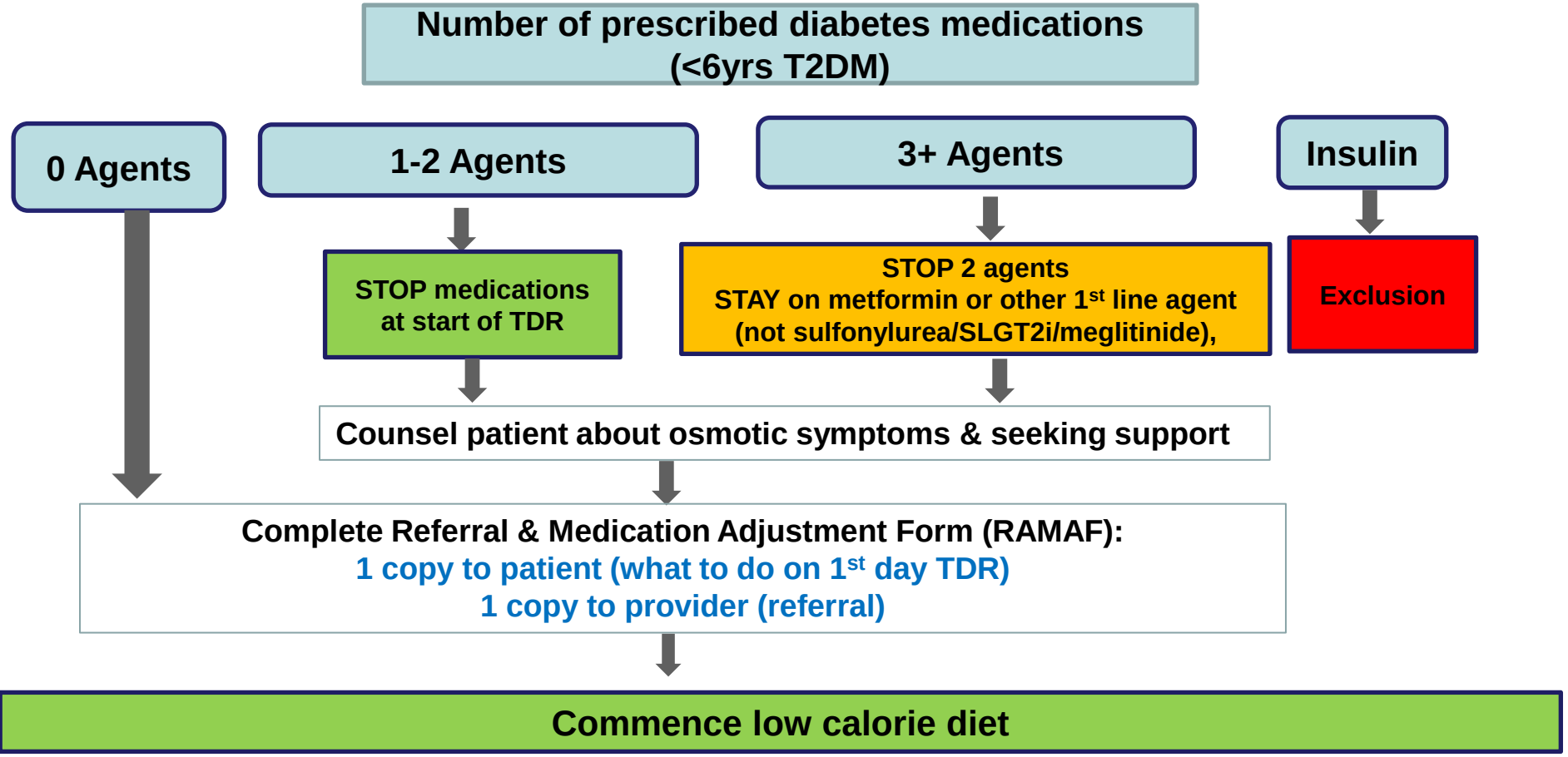
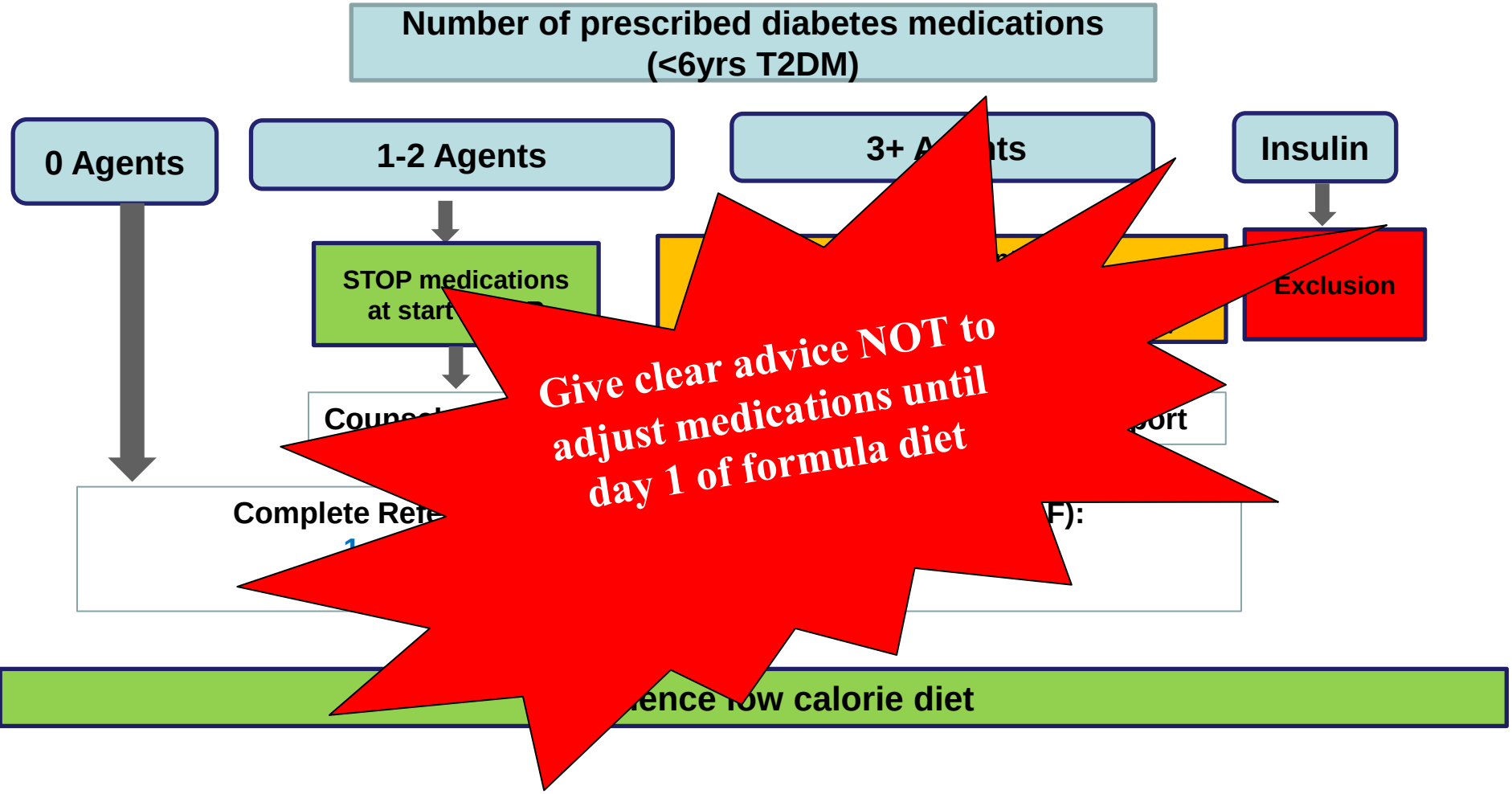
Medication adjustment protocols

- The following medication adjustment recommendations have been formulated by an Expert Advisory Group including the lead investigators of the DiRECT and DROPLET trials, consultant diabetologists and primary care clinicians.
- The recommendations are designed to be **safe, evidence-based and pragmatic.**
- They **do not replace clinical judgement** and constitute guidance only. Clinical responsibility remains with the referring GP practice

Deprescribing glucose medication

- Blood glucose levels drop significantly on day 1 of TDR so patient needs to stop meds on day 1 of starting the formula diet.
- If on 1 or 2 glucose lowering meds, stop them all.
- If on 3 or more meds, stop two and continue metformin
  (or a DPP4i “gliptin” or pioglitazone if not on metformin)
- **Sulfonylureas, meglitinides or SGLT2 inhibitors must not be used during Phase 1 for safety reasons**


Number of prescribed diabetes medications (<6yrs T2DM)
0 Agents
1-2 Agents
3+ Agents
Insulin
STOP medications at start of TDR
STOP 2 agents
STAY on metformin or other 1st line agent (not sulfonylurea/SLGT2i/meglitinide),
Exclusion
Counsel patient about osmotic symptoms & seeking support
Complete Referral & Medication Adjustment Form (RAMAF):
1 copy to patient (what to do on 1st day TDR)
1 copy to provider (referral)
Commence low calorie diet


Number of prescribed diabetes medications (<6yrs T2DM)
0 Agents
1-2 Agents
3+ A ts
Insulin
STOP medications at start
Exclusion
Give clear advice NOT to adjust medications until day 1 of formula diet

Glucose Deprescribing Examples

RED = STOP GREEN= CONTINUE

n.b. all patients have HbA1c <87mmol/mol on referral

Anja is on **metformin**

Baljit is on **metformin** and **gliclazide**

Clare is on **metformin**, **empagliflozin**, and **liraglutide**.

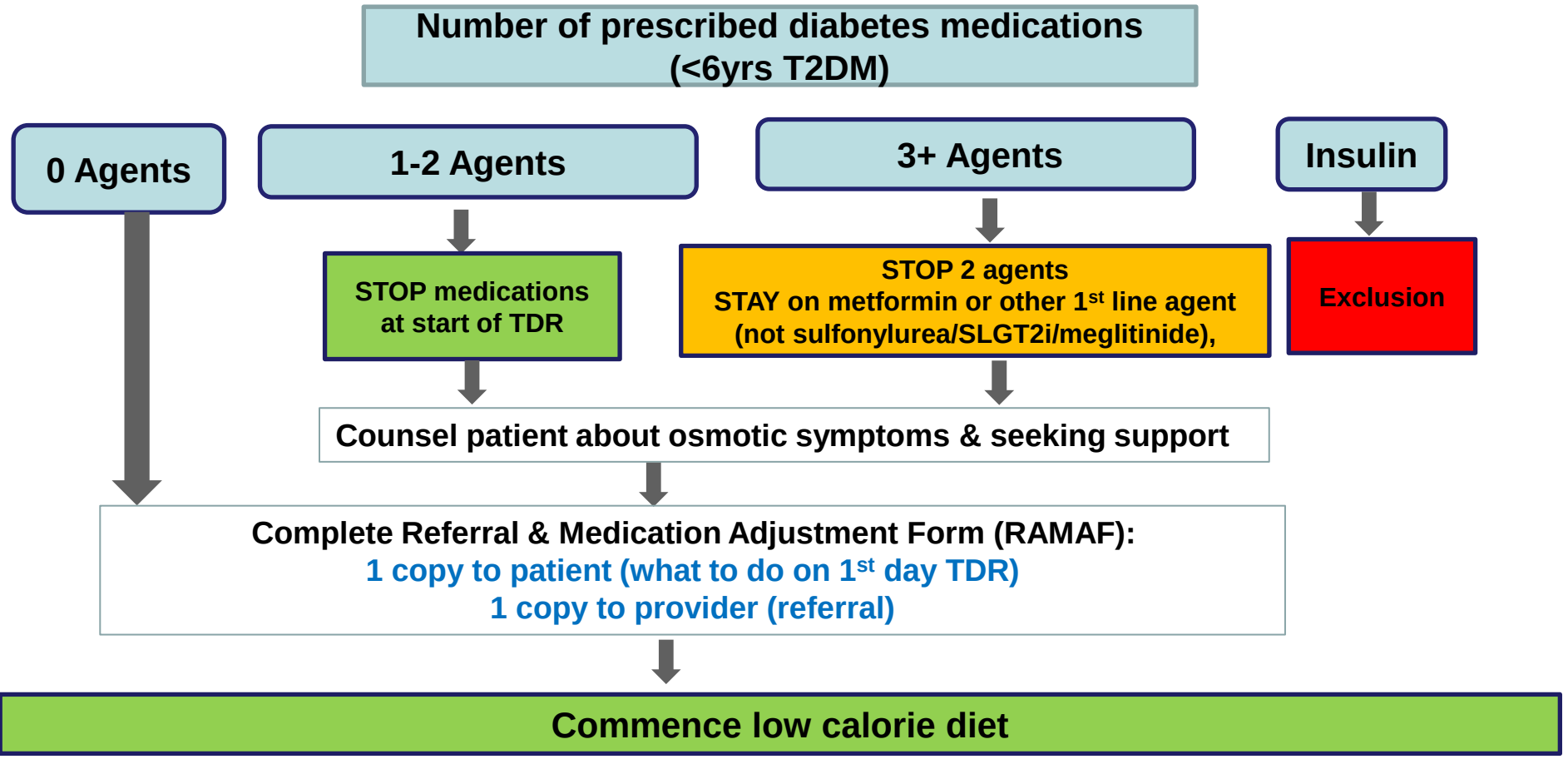
David is on **metformin**, **sulfonylurea** and **DPP4 inhibitor**

Emma is on **gliclazide**, **SGLT2 inhibitor** and **GLP-1 analogue**

Franz is on **sulfonylurea**, **SGLT2 inhibitor**, and **DPP4 inhibitor**

Gemma is on **DPP4 inhibitor**, **pioglitazone** and **SGLT2 inhibitor (keep 1 green)**

Henri is on **metformin**, **pioglitazone**, **SGLT2 inhibitor** and **GLP-1 analogue**



Glucose monitoring at all group sessions:

- **Under 15 mmol/l: No action**
- **Between 15.0 - 19.9 mmol/l over 2 Sessions: Provider will contact the Service User's GP practice**
- **20.0 mmol/l or higher: Same-day contact with the Service User's GP practice team** (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day)

GP practice review with repeat HbA1c
at 6 months and 12 months after starting programme

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Restarting glucose medication

If Momenta flags that blood glucose is above 15 or GP practice find that HbA1c at 6 or 12 months has risen:

- Metformin first line and is also safe in Phase 1
- Pioglitazone or DPP4 inhibitors are also safe in Phase 1
- GLP-1 analogues are safe in Phase 1 and can be restarted

- **Reminder: Sulfonylureas, meglitinides or SGLT2 inhibitors must not be used during Phase 1**

Glucose represcribing examples

Alice is still doing the low calorie diet (Phase 1)

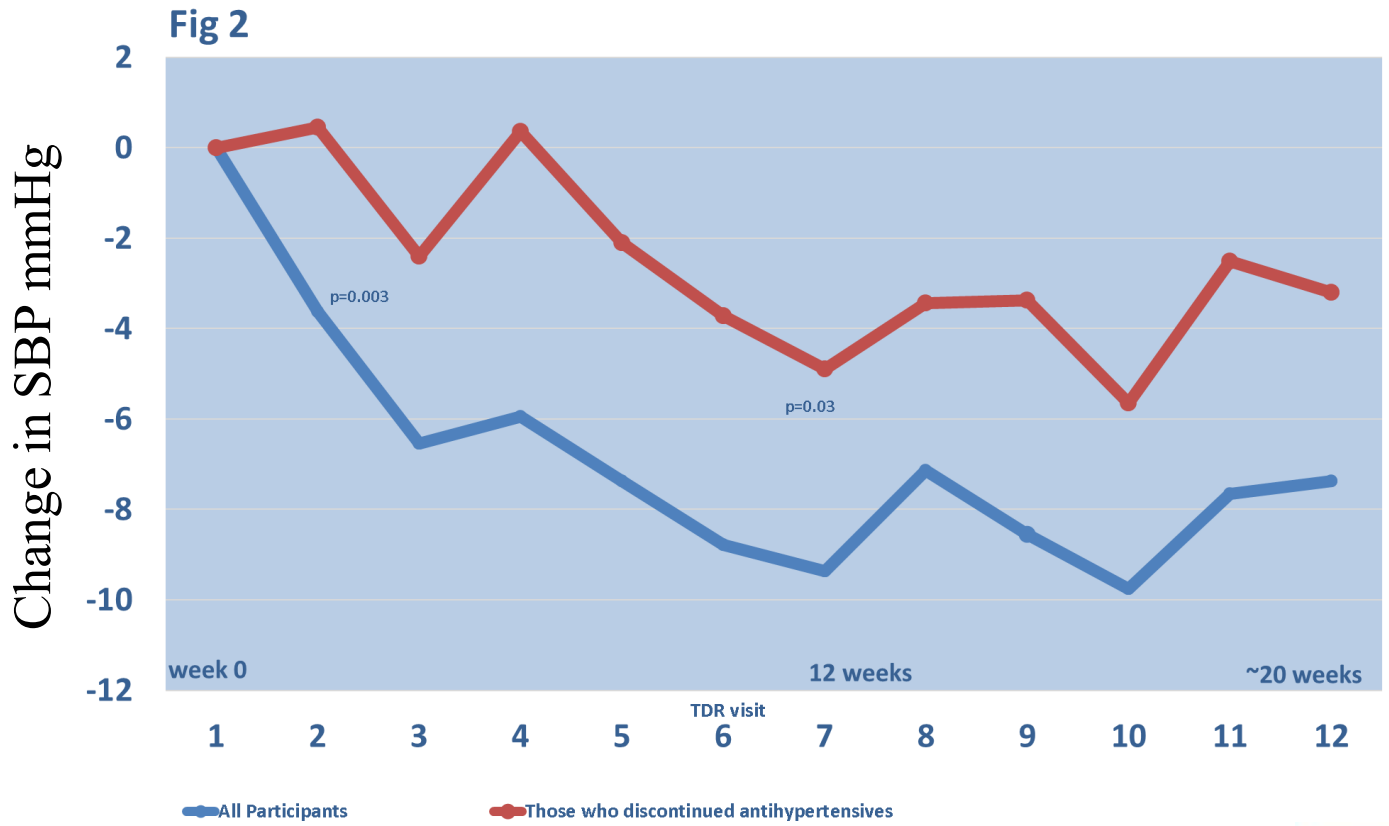
- On metformin (gliclazide and empagliflozin were deprescribed)
- **Gliclazide and empagliflozin CANNOT be restarted as c/i in Phase 1 (formula diet)**
- **Start DPP4i (or if intolerant GLP-1)**

Ben has just finished the low calorie diet phase

- On metformin (empagliflozin and liraglutide were deprescribed)
- **Can restart either empagliflozin or liraglutide**

Medication adjustments rationale: BP

Data from DiRECT



Discontinued anti - hypertensives

All

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Stopping/adjusting BP lowering agents

On referral:

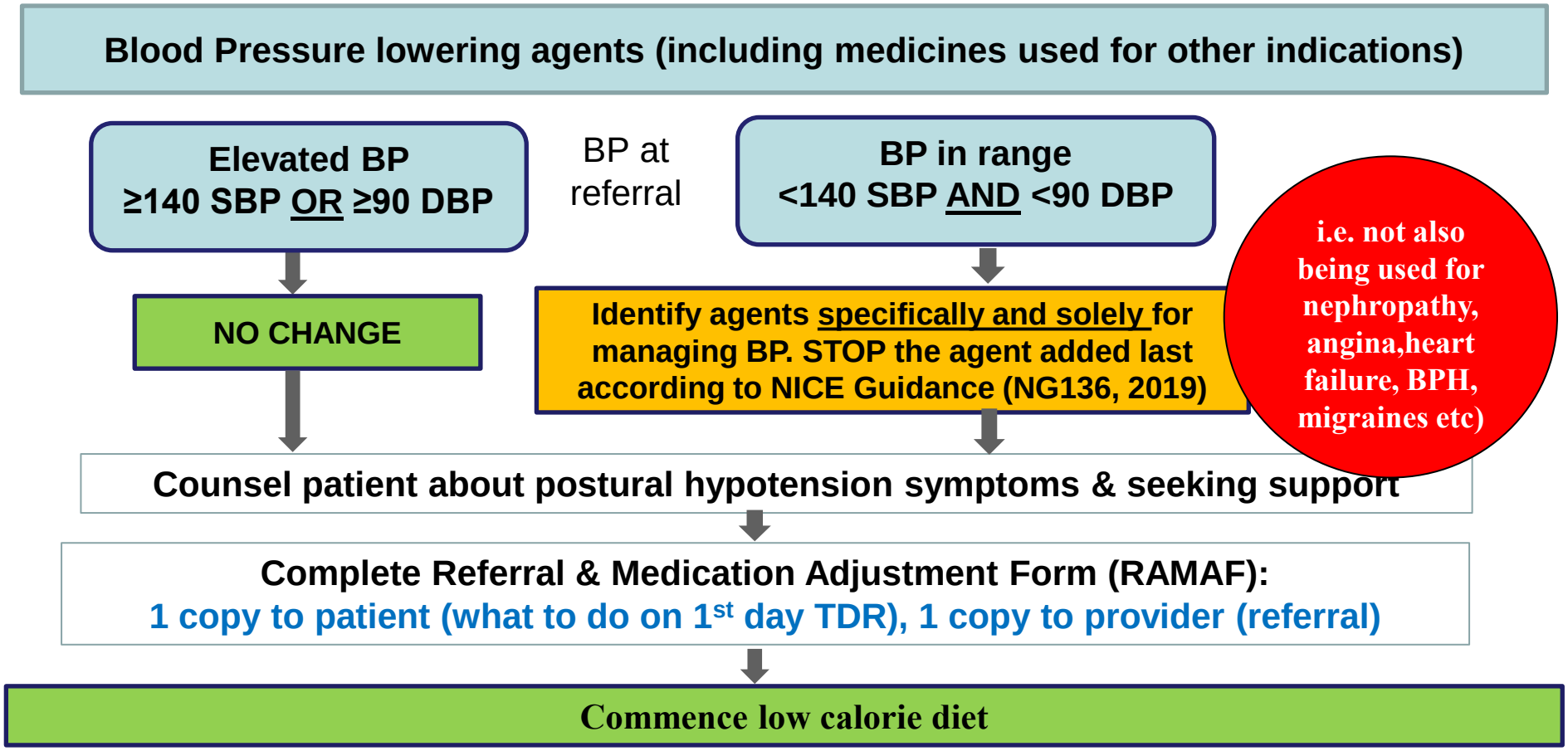
- **If BP is raised**
  - (Systolic≥140mmHg **or** diastolic≥90mmHg)
  - *Make no changes to BP-lowering agents*
- **If BP is in range**
  - (Both systolic<140mmHg and diastolic<90mmHg)
  - *Stop/adjust **one** BP-lowering agent*

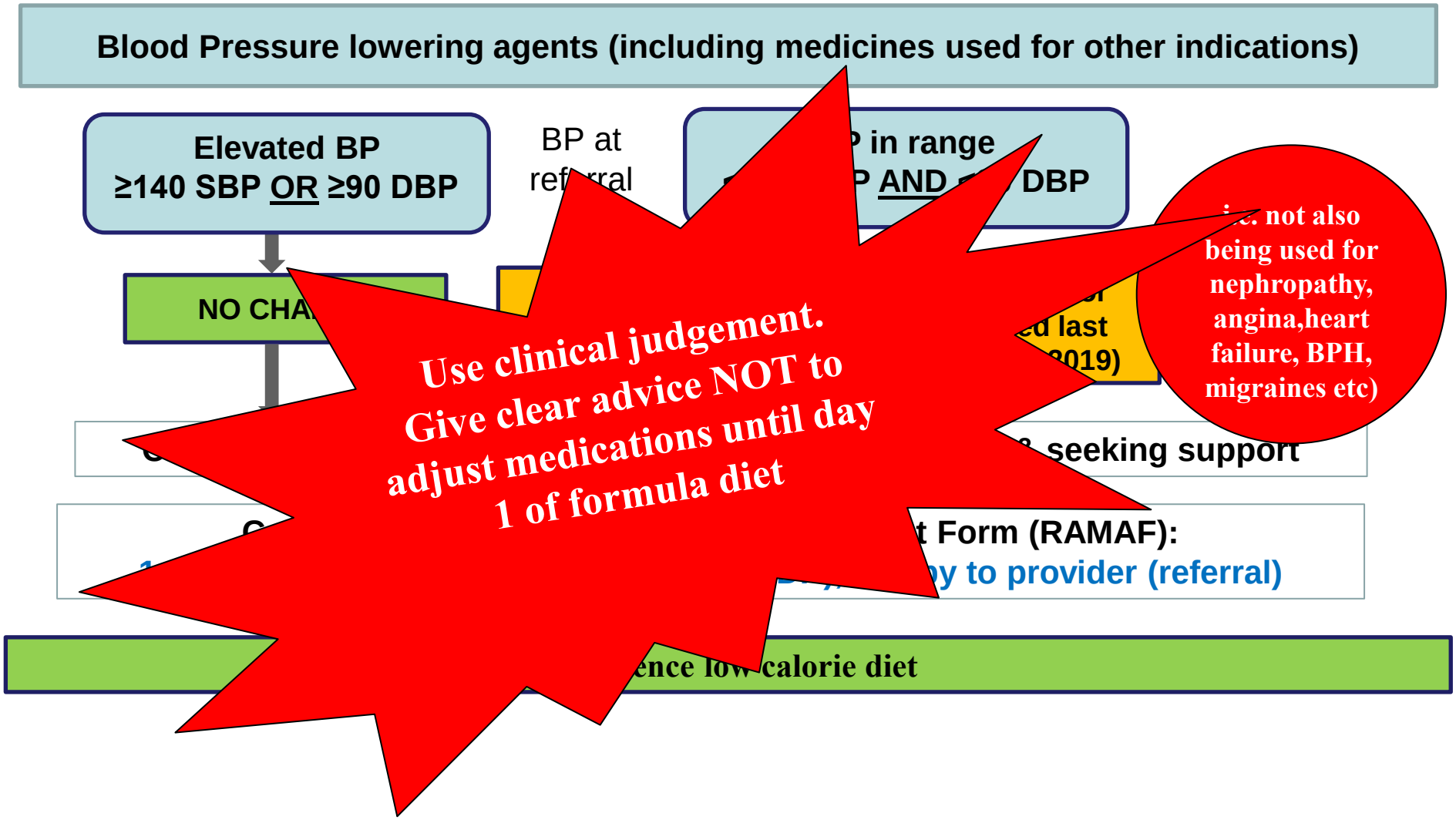
Advise patient to make the changes **on the first day of the formula diet**

- <u>not before</u>

Which BP medication to adjust?

- Check notes, check with patient if any of the BP medications are also prescribed for another reason
  - e.g. nephropathy, angina, heart failure, BPH, migraines
- Stop the agent that is *purely prescribed for BP & which would have been added last* according to current NICE guidelines.
- This would be (in order of stopping first):
  i. Spironolactone or alpha-blocker or beta-blocker
  ii. Calcium-channel blocker or Thiazide diuretic
  iii. ACE-inhibitor or Angiotensin receptor blocker
- If the patient is taking agents which affect blood pressure but ***all*** *are prescribed for other indications,* cautiously reduce the dose of one or more agent in discussion with the patient.


Blood Pressure lowering agents (including medicines used for other indications)
Elevated BP
≥140 SBP OR ≥90 DBP
BP at referral
BP in range
<140 SBP AND <90 DBP
i.e. not also being used for nephropathy, angina,heart failure, BPH, migraines etc)
NO CHANGE
Identify agents specifically and solely for managing BP. STOP the agent added last according to NICE Guidance (NG136, 2019)
Counsel patient about postural hypotension symptoms & seeking support
Complete Referral & Medication Adjustment Form (RAMAF):
1 copy to patient (what to do on 1st day TDR), 1 copy to provider (referral)
Commence low calorie diet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Use clinical judgement.
Give clear advice NOT to
adjust medications until day
1 of formula diet
seeking support
t Form (RAMAF):
y to provider (referral)
ence low calorie diet

BP deprescribing examples

RED = STOP GREEN= CONTINUE AMBER = CONSIDER

Patients A-F have BP in range.

Anja is taking **ramipril 10mg** (for BP solely –no other indications)

Baljit is taking **ramipril 10mg** (for BP solely) and **amlodipine 10mg** (for BP solely)

Claire is taking **ramipril10mg** (previous MI), **amlodipine 10mg** (for BP solely), **indapamide mr1.5mg** (for BP solely), **bisoprolol 10mg** (previous MI)

David is taking **ramipril 10mg** (for nephropathy) **reduce dose depending on BP**

Ed is taking **propranolol 40mg bd** (for migraine prophylaxis), **doxazosin 2mg** (for BPH)

consider reduce dose of one or both or switch migraine prophylaxis medication

Francis has BP 162/91 on ramipril 5mg, and amlodipine 5mg – keep both as BP above target – maybe able to stop amlodipine once weight loss and BP <140/90

Blood Pressure lowering agents (including medicines used for other indications)

Elevated BP
≥140 SBP OR ≥90 DBP

BP at referral

BP in range
<140 SBP AND <90 DBP

i.e. not also being used for nephropathy, angina,heart failure, BPH, migraines etc)

NO CHANGE

Identify agents specifically and solely for managing BP. STOP the agent added last according to NICE Guidance (NG136, 2019)*

Counsel patient about postural hypotension symptoms & seeking support

Complete Referral & Medication Adjustment Form (RAMAF):
1 copy to patient (what to do on 1st day TDR), 1 copy to provider (referral)

Commence low calorie diet

BP monitoring at all group sessions (Remote: Only for those on BP lowering agents at referral)

- **SBP<90 or DBP<60 or postural symptoms reported: *Repeat above process***
- **SBP 160-179 OR DBP 100-119 : *Increase or uptitrate as per NICE Guideline***
- **SBP ≥180 OR DBP ≥ 120: Same day contact with GP practice. *Increase/uptitrate per NICE***

* Order of stopping first: (i) Spirinolactone or alpha blocker or beta blocker (ii) Thiazide diuretic or calcium channel blocker (iii) ACE inhibitor or Angiotensin receptor blocker

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Further adjustment of BP medication

Review: Blood pressure is <u>too low</u>

(<90/60 or postural symptoms)

- Review current medications that affect BP
- Stop/reduce the *next agent being used solely for managing BP*
- If prescribed for reasons other than BP alone, reduce/stop one of these agents (may need to seek specialist advice)

Further BP adjustment examples

Patients A-F BP now too low

Anja – (Ramipril was stopped): review again – any meds that can lower BP missed? If not, usual advice for hypotension and *may have to stop LCD*

Baljit is now only taking ramipril 10mg (for BP solely) having stopped amlodipine **so stop ramipril**

Claire is taking ramipril 10mg (previous MI), amlodipine 10mg (for BP solely), indapamide mr1.5mg (for BP solely), bisoprolol 10mg (previous MI). Stopped indapamide initially – **so now stop amlodipine**

David (ramipril 10mg (for nephropathy) - **reduce dose further – *if already on lowest dose seek advice***

Ed is taking propranolol 40mg bd (for migraine prophylaxis), doxazosin 2mg (for BPH) **consider reduce dose of one or both *or switch migraine prophylaxis medication***

Francis continued on ramipril 5mg, and amlodipine 5mg – stop amlodipine first, then reduce/stop ramipril if BP still too low.

Further adjustment of BP medication

Review: Blood pressure is <u>too high</u>

(160/100 to 179/119 mmHg (systolic and/or diastolic) at 2 sessions OR 180/120 mmHg or higher (systolic and/or diastolic) on 1 occasion

- Restart/ increase any previously stopped/adjusted agents.
- Prioritise restarting those *used for other indications*
- Then any previously stopped/adjusted agents for managing blood pressure alone
- Follow NICE guidance for antihypertensive therapy

Further BP adjustment examples

Patients A-F BP now too high

Anja (Ramipril was stopped): restart ramipril and titrate as per usual until BP optimised as on for BP alone

Baljit (amlodipine 10mg was deprescribed, continued ramipril 10mg) – restart amlodipine 5mg and increase back to 10mg dependant on BP

Claire

- amlodipine 10mg (for BP solely), or indapamide mr1.5mg (for BP solely) was stopped
- continued ramipril10mg (previous MI) and bisoprolol 10mg (previous MI)
- restart the one that was stopped: if amlodipine restart at 5mg and increase back to 10mg dependant on BP

David ramipril 10mg (for nephropathy) dose was reduced – increase dose back up

Ed was taking propranolol 40mg bd (for migraine prophylaxis), doxazosin 2mg (for BPH) – if propranolol was changed for alternative migraine treatment consider starting ACE or Calcium channel blocker – if it was reduced try increasing back to 40mg bd

Francis (continued ramipril 5mg, and amlodipine 5mg) – increase ramipril, then amlodipine if BP still too high

Other meds which may need adjusting

Consider: “If someone changed their diet significantly or lost significant weight would any medication doses need adjustment?”

- It is the responsibility of the referrer to ensure processes are in place for any applicable medications to be adjusted as needed.
- If in doubt, discuss with a pharmacist colleague
- Liaise with specialist clinic if receiving treatment elsewhere esp if parenteral drug e.g. biological treatments.

- Commonly used oral medicines which may require adjustment include:
  - Warfarin – advise warfarin clinic patient taking part
  - DOACs
  - Digoxin
  - Phenytoin
  - Ciclosporin

Making successful referrals: 4 steps

1. Identify eligible participants
   - Searches: EMIS & SystmOne
   - *Optional manual screening*
2. Invite: Raise awareness, self-assess readiness, contact GP practice https://momentanewcastle.com/patient-lcd-newcastle
3. Discuss and refer
   - Can be telephone or in-person appointment
   - Inform patient clearly of future Medication Adjustments (Day 1 TDR)
   - Give patient a copy of the Referral and Medication Adjustment Form (RAMAF)
4. Send RAMAF to Momenta at momenta.nenc-lcd@nhs.net

Ad hoc referrals: This process can be used at annual / other reviews *n.b. patients may not have a nearby in-person group*

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Search & referral form demonstration

https://momentanewcastle.com/hcp-videos-nenc

Go to 42 mins 19 secs for EMIS and 48 mins and 11 secs for SystmOne

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Helpful links and emails

Links

- Information page for participants
  - https://momentanewcastle.com/patient-lcd-newcastle
- Referrer resources for health care professionals (and links to videos)
  - https://momentanewcastle.com/hcp-lcd-newcastle

Email contacts

- Secure email to send referrals to Momenta

  momenta.nenc-lcd@nhs.net
- Queries: Project lead dietitian Alison.barnes28@nhs.net

  Contract Manager: jon.scott@momentanewcastle.com

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Thank you for your time!
Q&A?

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Momenta:

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jon.scott@momentanewcastle.com

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