

“Checklist Manifesto” (preparing for OIT)

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Nothing prepares you to be a pilot, but becoming a pilot prepares to do other complicated activities.

- Only some of your allergy training prepares you to do oral immunotherapy,
- FAST training and ongoing “hanger talk” allow you to gradually increase your capabilities
- Start with simple patients, simple foods, uncomplicated stories
- 4 year old, egg allergy, hives only

Nothing is an emergency, everything is a procedure.

Checklist of checklists

- Office ready checklist
- Food ready checklist
- Doctor ready checklist
- Staff ready checklist
- Initial evaluation checklist
- First dose check list
- Escalation dose checklist
- Maintenance checklist
- Yearly follow-up checklist
- Long term checklist

Checklist construction

- Many checklists
- Only 5 items per list
- Otherwise “checkitis”



Stall Warning Device







MD

3

05

914

3

18113

r, MD

4743

36099

: 183367

erton, PA-C

5803462

A156337

34694 (expired)

Numbers

IPI 1225207178

AX ID 320220938

CARE R1149101

43100/ MEDICARE PTAN R149100

eratory Client ID # 310207

eratory Client ID # 5610

eratory Client ID # 31005584

Bathrooms

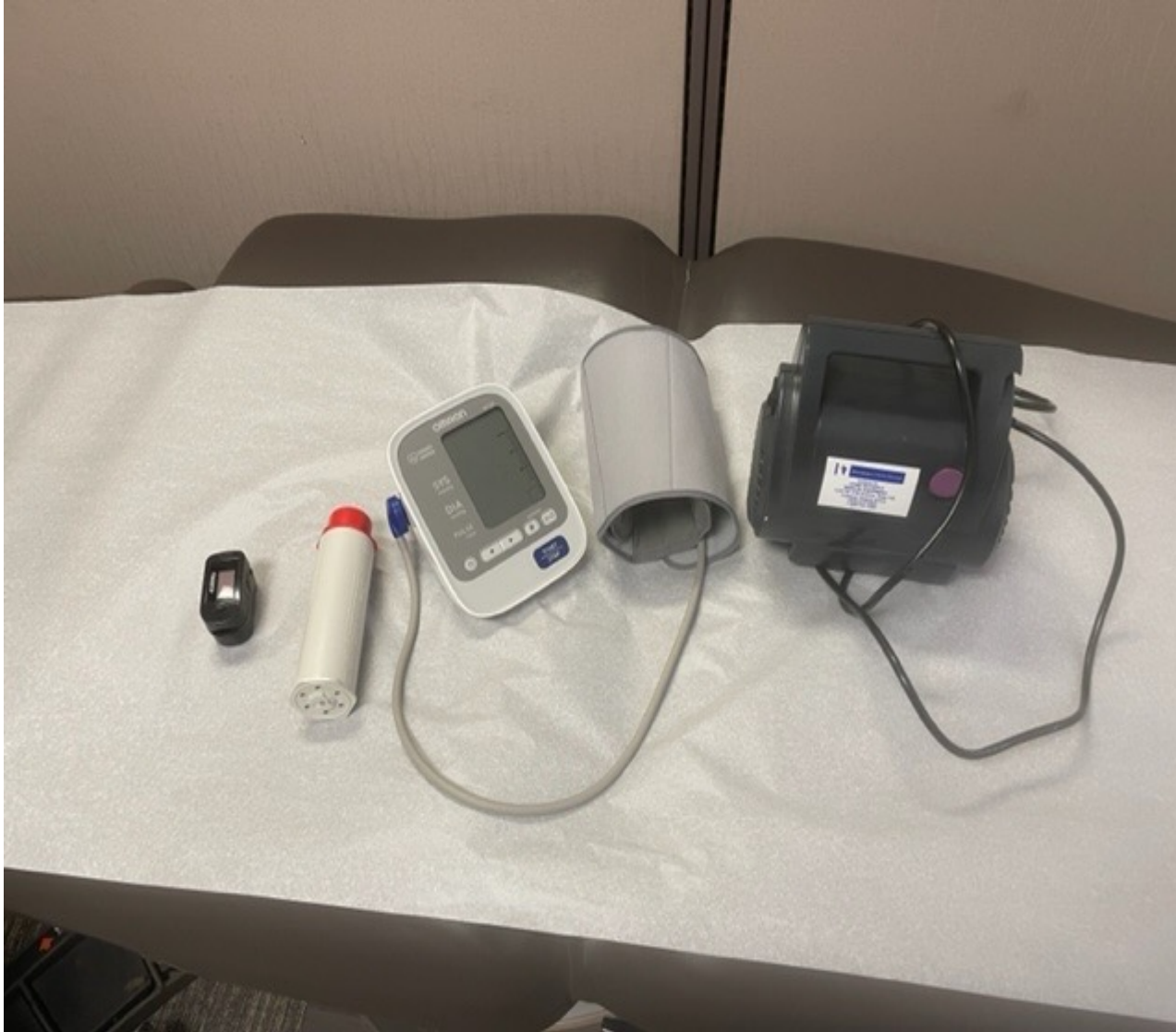
Pilot in Command



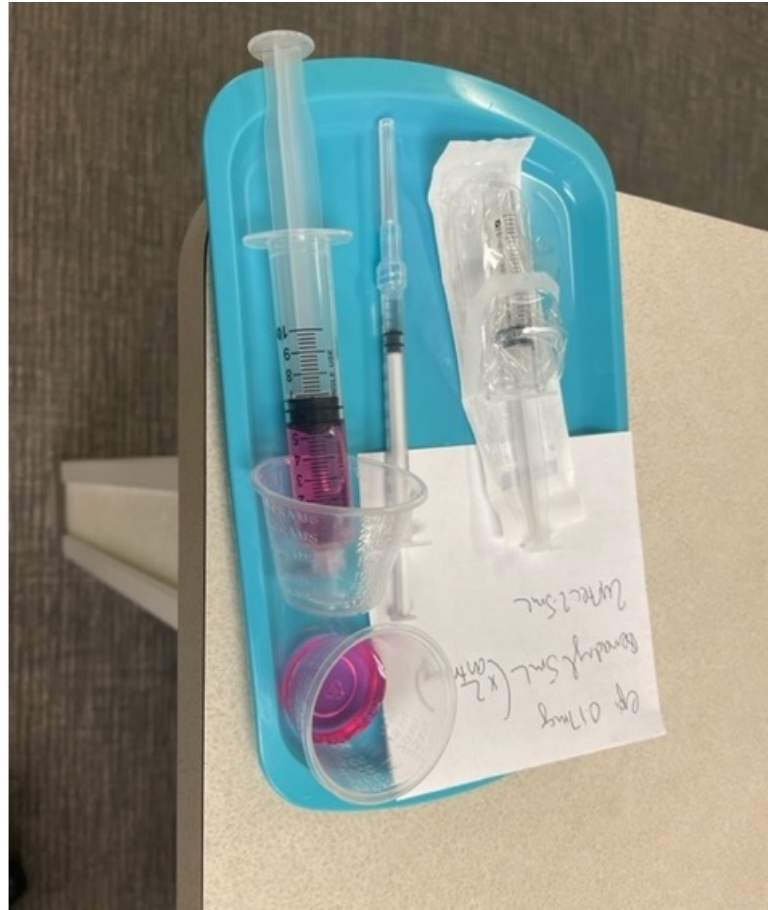
Nothing is an emergency, everything is a procedure



Attitude, altitude, attitude, heading,



Get Ready To Deal With Reactions



Food ready checklist

- Know your source before patient comes in
- Changing sources difficult
- Fresh foods such as milk, eggs need to be brought in or kept in refrigerator
- Weight or protein content

Doctor ready checklist

- Doctor present and will be here during the entire challenge
- Designated late doctor on schedule
- 2 sets of eyes on all decisions
- Dual independent confirmation of dose
 - Picture, weight, volume, concentration

Staff ready checklist

- Scheduled staff
- Training staff
- Alternate staff

Initial evaluation checklist

- History, physical, skin tests, lab tests
- Procedure to be followed
- Pros and Cons
- Decision to undergo OIT
- Who or what can defeat you?

| History | Skin test | Immunocap | Component | Approach |
|-----------------------------|--|---|-----------|--|
| Positive diagnostic history | ➤ 7 mm 3-6 mm 0-2 mm Not done | Class 3-6 Class 1 and 2 Class 0 Not done | | Avoid/slow challenge-OIT (2x -14 step) Avoid/slow challenge-OIT (2x -14 step) Avoid/rapid challenge (10x – 4 step) Avoid/do work up |
| Suggestive or Unsure | ➤ 7 mm 3-6 mm 0-2 mm Not done | Class 3-6 Class 1 and 2 Class 0 Not done | | Avoid/slow challenge-OIT (2x -14 step) Avoid/modified challenge-OIT (3x-7 step) Avoid/Rapid challenge Avoid/do work up |
| Negative | ➤ 7 mm 3-6 mm 0-2 mm Not done | Class 3-6 Class 1 and 2 Class 0 Not done | | OK to consume/rapid challenge OK to consume/rapid challenge OK to consume OK to consume |
| No history of exposure | ➤ 7 mm 3-6 mm 0-2 mm Not done | Class 3-6 Class 1 and 2 Class 0 Not done | | Avoid/slow challenge-OIT (2x -14 step) Avoid/modified challenge-OIT (3x-7 step) Avoid/Rapid challenge (10x - 4 step) Avoid/do work up |

Scheduling

- Multiple appointments made at a time
- Feel free to cancel if.....
- Goal
 - Finding the threshold
 - Up-dosing – determine rate of increase
 - Maintenance stage
 - Graduation stage
 - Ad lib diet
 - Daily
 - Positive control with I-phone

Escalation checklist

- Review history
- Review skin test or lab results
- Review flow sheet
- Establish rate of increase

Challenge protocols in mg of peanuts for expected positive challenges

- 2x protocol – 14 step
- .25, .50, 1, 2, 4, 8, 16, 32, 64, 128, 256., 500, 1000, 2000, mg
- Occasionally we use a 1.5X protocol
- Occasionally a 2 up – 1 back protocol
- Occasionally a 1.25x protocol at home by TELEMED

Challenge protocols in mg of peanuts

- 3x protocol – 7 step
- 10, 30, 100, 300, 1000, 3000, 10,000 mg

Challenge protocols in mg of peanuts for expected positive challenges

- 2x protocol – 16 step
- .25, .50, 1, 2, 4, 8, 16, 32, 64, 128, 256., 500, 1000, 2000, 4000, 8,000
- Initial placebo effect
- These low starting doses occasionally elicit a positive response
- Most patients will have a positive challenge before the 6th dose
- 17/128 patients had no endpoint – were they negative? Or did I desensitize them? Does it matter?

Challenge protocols in mg of peanuts

- 3x protocol – 7 step
- 10, 30, 100, 300, 1000, 3000, 10,000 mg
- Not all patients require a positive food challenge
- 13% of patient who pass this protocol will have a positive challenge the following day to a composite of these doses.
- 28% of patients using this protocol will have a severe reaction
- One death has occurred with this protocol
- US investigators used adrenalin twice as often as their European colleagues in the Aimmune protocol.

Home instruction checklist

- At home conditions are different:
 - exercise, uri, other antigens, menstrual periods, adequate supervision
- Adrenalin kit
- Action plan
- Phone numbers
- Discussion of late “out of window” reactions
- Vacation or “camp” plans
- Take home doses

3-5 year maintenance checklist

- Reactions can occur anytime in the process
- Continue to have adrenaline available
- “Positive control” systems approach
- Triple challenge
- “If you stop” discussion

Long term checklist

- Children take over decisions
- High drop out rate
- “Positive control” approach
- Carry adrenalin
- Not cured

Maxims

- Once a no-go, always a no-go
- There are old pilots and bold pilots but no old bold pilots
- Better on the ground wishing you were in the air than in the air and wishing you were on the ground
- One mistake can be overcome, multiple mistakes at the same time can kill you.
- Aviate, navigate communicate
- Write, repeat, follow
- Double and triple redundancy is the art of flying and OIT

Mistake log

- Invite phone calls
- Learn from observations, mistakes, other's mistakes
- Keep re-designing your checklists
- Admit this is an emerging therapy
- “Strive for perfection and you will find excellence along the way”
 - Vince Lombardi