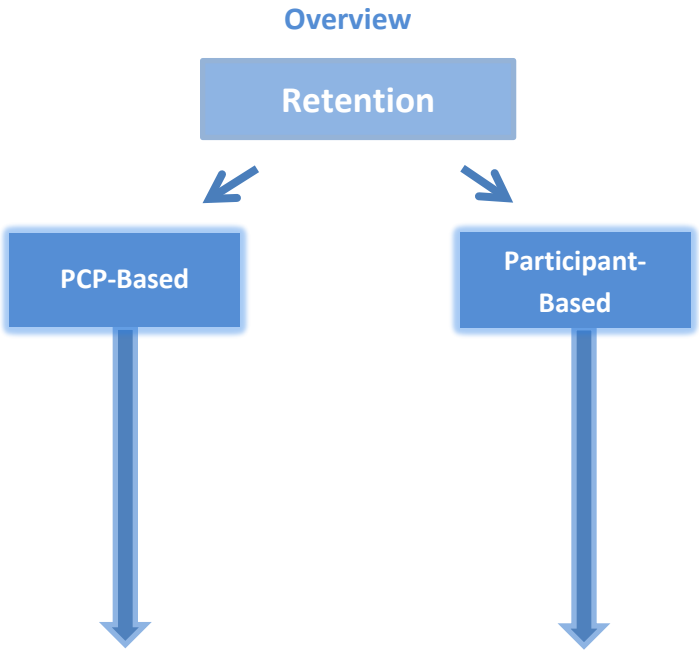
Overview of Retention Strategies for D2d, July 2015

Objective: To maximize participant retention and adherence to study procedures, the RRS has prepared an overview of retention strategies, structured as a tool to facilitate discussion within your team on how to optimize and individualize your approaches to retention. The RRS encourages you to provide additional examples and ideas that we can incorproate and share study-wide.



1. Keep your clinician base informed about general study progress

Tools: Clinician Newsletter

2. Keep participant's PCPs generally informed about medical issues specific to their patients.

This requires direct PCP-INVESTIGATOR-participant communication:

A. Outside labs suggest progression to diabetes, but study labs do not (PCP wants to start metformin)

Tools: example communication template

B. Outside vitamin D level is low. PCP wants to give high dose vitamin D (e.g. "My doc checked my levels, I *know* I'm on placebo!")

Tools: handout "Talking points about vitamin D and calcium"

Think, what can we 'GIVE BACK' to participants? Think, what motivates participants to keep coming back?

A. Education at every opportunity

- The annual exam isn't just an exam; is retention being optimized at this visit?
- Twice a year educational sessions -- attendance/promotion/quality of interactions?

B. Communication

- Participant newsletters

C. Align expectations

- Participant information brochure
- Business/Appointment Cards

D. Relationship with study team

- Track 'Things of Interest' (e.g. important people and life events, vacations)
- Brief Notes by PI to Participants
- Ensure participant identifies with team/multiple members of team (and not just a single person)

Primary Care Physician – Based Retention

✓ *Keep your clinician base informed about general progress of D2d.*

- Rationale: primary care is a critical part of the D2d journey

How do I do this?

- Use the ***D2d Clinician Newsletter***, issued annually. Found at D2d portal under the 'Newsletters' tab.

- **Have D2d team discussions and establish action plan with DRI** (directly responsible individuals).
  - Are you currently disseminating the D2d clinician newsletter to your PCP colleagues or physicians that care for your trial participants or to those that serve as your source of future participants?
    - If not, why not?
  - If you agree to disseminate the D2d Clinician Newsletter or other form of communication regularly to your clinician base, establish:
    a. Responsible person and frequency: _____
    b. Triggers/reminders to do this: _____

✓ *Keep the PCPs of participants informed with emphasis on diabetes testing.*

- *Rationale*: It is very likely that PCP will not remember that their patient is in D2d and the participant may not inform his PCP of the D2d study restrictions.
- PCPs that are updated regularly are more likely to be more engaged with D2d and consult with investigators if there are questions.

How do I do this?

- **A letter should be sent to the PCP after each study visit with glycemic testing (semi-annual, annual, unscheduled\confirmatory).** Template letters to the PCP are available on the portal (MOP 17). While there are standard D2d-provided templates (MOP 17) to report results to the PCP, it is important for the clinical team member to communicate with the PCP and participant as needed, especially if there is a discrepancy on diagnosis (see next section).

✓ *Keep the communication channels open and inform PCPs about specific issues regarding participants.*

- *Rationale:* Medical issues that arise during D2d require direct PCP ← INVESTIGATOR → PARTICIPANT communication. The two most critical issues are
  1. Diagnosis of diabetes outside of the study and use of diabetes medication by PCP
  2. High dose vitamin D supplementation.

How do I manage these issues?

1A. Labs done outside of D2d suggest progression to diabetes. Physician wants to start metformin.

Clinicians are screening for pre-diabetes/diabetes and may initiate therapy with metformin (or other diabetes medication) in pre-diabetes (5.7 to 6.4%) or early diabetes (e.g., A1c 6.5 to 7%)

⇒ **It is critically important that the participant returns for diabetes testing according to D2d protocol (MOP 18) BEFORE she starts any diabetes medication.**

1B. Labs done outside of D2d suggest progression to diabetes but D2d testing does not confirm diabetes. Physician still wants to start metformin.

⇒ **An honest and respectful conversation about whether the participant does or does not have diabetes requires clinician (i.e. site PI or study physician) to PCP communication**. See example below:

Site PI: "Hi Dr. XXX, Your patient, XXX, is doing well in the NIH-funded D2d study evaluating whether vitamin D can prevent the progression to diabetes in those at high risk of diabetes. We noted that the patient had a blood test when she saw you, showing an HbA1c of 6.5% and that you gave her a prescription for metformin. We repeated her testing within the D2d study and her results came back showing no progression to diabetes thus far (i.e., HbA1c < 6.5% and a fasting plasma glucose < 126 mg/dL). The study follows ADA guidelines for the diagnosis of diabetes and requires confirmation before we initiate metformin. With your ok, we would like to ask the patient to not start the metformin, and we will continue to test her very closely every 6 months and we will let you know if our testing is consistent with diabetes. If you agree, I'll let the patient know you and I communicated and that we are in agreement with holding off on the metformin. Thank you."

PCP: "Sure that's fine, XXXX. Can you please enter a note in the flow sheet?"

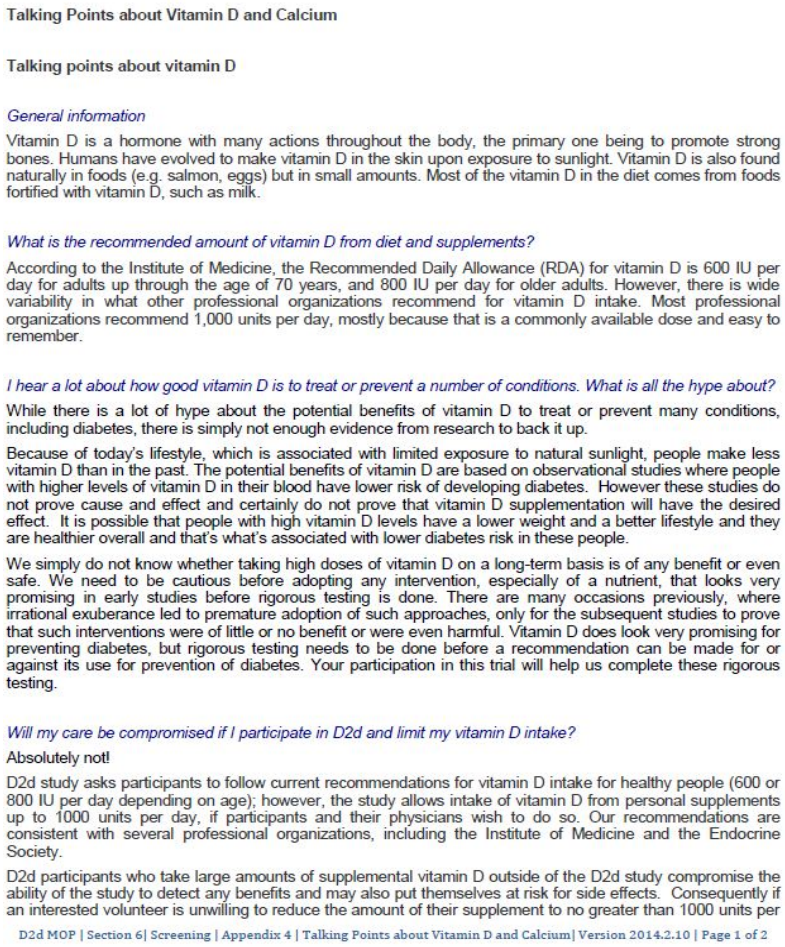
⇒ *Team discussion:* Who is handling these more 'sensitive' clinical conversations with the PCP?
While there are standard D2d-provided templates (MOP 17) for when patients do progress to diabetes, it is probably important for the clinical team member to communicate with the PCP and patient if there is a discrepancy on diagnosis, as in the example given.

2. Labs done outside of D2d show low vitamin D level. Physician wants to start high-dose vitamin D.

Clinicians are screening for vitamin D status and may initiate therapy with high dose vitamin D.

⇒ **An honest and respectful conversation about whether the participant does or does not have vitamin D deficiency requires clinician (i.e. site PI or study physician) to PCP communication**.

- Please, refer to "Talking Points about Vitamin D and Calcium" handout (MOP 6)
- Please, reiterate concept of equipoise and purpose of study.
- Perhaps incorporate dialogue early on about what their PCP might find if they test their vitamin D levels and what bearing that has on study participation.



Talking Points about Vitamin D and Calcium

Talking points about vitamin D

General information

Vitamin D is a hormone with many actions throughout the body, the primary one being to promote strong bones. Humans have evolved to make vitamin D in the skin upon exposure to sunlight. Vitamin D is also found naturally in foods (e.g. salmon, eggs) but in small amounts. Most of the vitamin D in the diet comes from foods fortified with vitamin D, such as milk.

What is the recommended amount of vitamin D from diet and supplements?

According to the Institute of Medicine, the Recommended Daily Allowance (RDA) for vitamin D is 600 IU per day for adults up through the age of 70 years, and 800 IU per day for older adults. However, there is wide variability in what other professional organizations recommend for vitamin D intake. Most professional organizations recommend 1,000 units per day, mostly because that is a commonly available dose and easy to remember.

I hear a lot about how good vitamin D is to treat or prevent a number of conditions. What is all the hype about?

While there is a lot of hype about the potential benefits of vitamin D to treat or prevent many conditions, including diabetes, there is simply not enough evidence from research to back it up.

Because of today's lifestyle, which is associated with limited exposure to natural sunlight, people make less vitamin D than in the past. The potential benefits of vitamin D are based on observational studies where people with higher levels of vitamin D in their blood have lower risk of developing diabetes. However these studies do not prove cause and effect and certainly do not prove that vitamin D supplementation will have the desired effect. It is possible that people with high vitamin D levels have a lower weight and a better lifestyle and they are healthier overall and that's what's associated with lower diabetes risk in these people.

We simply do not know whether taking high doses of vitamin D on a long-term basis is of any benefit or even safe. We need to be cautious before adopting any intervention, especially of a nutrient, that looks very promising in early studies before rigorous testing is done. There are many occasions previously, where irrational exuberance led to premature adoption of such approaches, only for the subsequent studies to prove that such interventions were of little or no benefit or were even harmful. Vitamin D does look very promising for preventing diabetes, but rigorous testing needs to be done before a recommendation can be made for or against its use for prevention of diabetes. Your participation in this trial will help us complete these rigorous testing.

Will my care be compromised if I participate in D2d and limit my vitamin D intake?

Absolutely not!

D2d study asks participants to follow current recommendations for vitamin D intake for healthy people (600 or 800 IU per day depending on age); however, the study allows intake of vitamin D from personal supplements up to 1000 units per day, if participants and their physicians wish to do so. Our recommendations are consistent with several professional organizations, including the Institute of Medicine and the Endocrine Society.

D2d participants who take large amounts of supplemental vitamin D outside of the D2d study compromise the ability of the study to detect any benefits and may also put themselves at risk for side effects. Consequently if an interested volunteer is unwilling to reduce the amount of their supplement to no greater than 1000 units per

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See document on the portal in the Manual of Procedures, section 6.

Participant – based retention

✓ *Track 'things of interest."*

- Rationale: getting to know the participant fosters long-term relationship.

How do I do this?

- **Make note of things of interest in the participant binder, and follow up at the next visit**. Participants appreciate knowing someone listened to them. For instance if participant says something about an upcoming vacation, or a significant event in their life, make note of it and inquire about it at the next visit.

  ✓ Utilize this information for interim follow up. For example, a site PI sends a short hand written note to the participant after most visits.

  "Dear XX,

  I am sorry I missed you at the month 6 visit of the D2d study. I was happy to hear from [name of coordinator] that you are doing well and that you plan to spend a week at the Cape. I am very pleased to report that the study is more than half way done with recruitment and the [name of site] is one of the top D2d sites nationally. Enjoy the rest of the summer and have a great time during your time off. I look forward to seeing you at the next visit.

  Name of PI"

  ⇒ *Team discussion:* How do you track items of interest with the participant, and take this 'memory' forward for next interactions? _____

- **Align expectations** about appointments, initiating diabetes medications and vitamin D/calcium limits.
  See example -> (on portal)

Utilize D2d business / appointment cards.

⇒ *Team discussion:* What are your current processes for confirming appointments, and for making sure that the participant comes to you before starting any diabetes medications?

- **Share Participant Newsletters** – are all your participants receiving these? Are new participants receiving previous newsletters?


D2d Vitamin D and type 2 diabetes NEWS

diabetes prevention research matters

In This Issue

A Note from the D2d Leadership

Partners in Research

D2dStudy.org

Tufts Medical Center

Newsletters are printed by the CC and sent to the sites for distribution.

⇒ *Team discussion:*
  - Are all your participants receiving these? If not, why not?
  - Are new participants receiving previous newsletters?

- **Consider Social media** as a possible retention tool – D2d is on Facebook and twitter.

⇒ *Team discussion:*
  - Have you asked your participants if they are use Facebook or twitter?
  - If they use social media, have you asked them to 'like' or 'follow' D2d to receive additional updates relevant to prediabetes and the study?
  - Is this part of your workflow?
  - Would you like it to be/how?

- Remember, **this is 'our' study**. Participant stories are part of the bigger story being formed. Participants are encouraged to share their own story on the D2d webpage.

  Example of one site's IRB-approved text sent to participants.

  "D2d participants like you are highly motivated individuals who are shaping the future of diabetes prevention. Your participation in D2d helps researchers find better ways to prevent diabetes. To find out about the experience of D2d participants, we encourage you to visit d2dstudy.org/participants.

  We would love to hear about your own experience as a D2d participant. You can share your motivation for joining D2d, a lifestyle change you made or any other D2d related experience. If you want, you can share a picture of yourself (e.g. pose with D2d memorabilia while on vacation). If you prefer, your name will be withheld and will not be shown with your comments.

  Did you know that D2d study is on Facebook and twitter? Please like us on Facebook and follow us on twitter to find out the latest news about the study and we encourage you to post your thoughts about the study.

  The D2d research team considers participants as partners and we deeply appreciate your commitment to the D2d study and we look forward to seeing you during the visits.

  www.D2dStudy.org | **Follow D2d:**

  ⇒ *Team Discussion*:
  - Do your participants know this?
  - How do you want to get this word out?

- Another way to look at RETENTION is our opportunity to **"Give Back"** to participants. They are consistently giving to us during the study – their consent, their blood, their information, and their stories.

  ⇒ *Team discussion:* Think of what we can keep giving back that will keep participants engaged with the study for the long-term.