Pediatric to Adult Transition of Care After Solid Organ Transplant

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Kids deserve the best.

Background

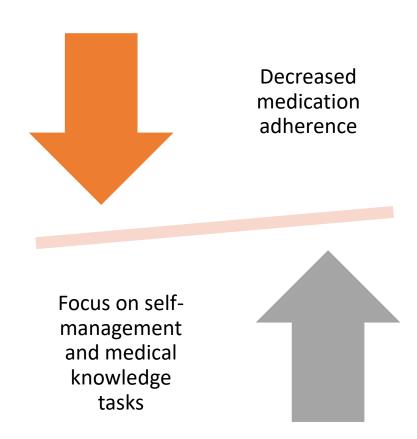
Definitions: Transition and Transfer

Transition continues to be a national practice and research priority

Adolescents and young adults (AYA) with functioning solid organ transplant

 2025: 8,000 – 12,000 transplant recipients in US based on estimates from SRTR and OPTN data

AYA are at the highest risk for nonadherence across the transplant lifespan Adolescence is recognized as a time of increased risk for poor health outcomes.



Contributing Factors to Non-Adherence

Development Stage

 Desire for autonomy, risktaking, limited executive function

Psychosocial Issues

 Depression, anxiety, peer pressure, stigma

Transition Gaps

 Poor communication between pediatric and adult teams

System Level Barriers

 Insurance changes, decreased parental involvement



Outcomes of Poor Transition



Higher rates of rejection and graft loss

18-25 year old group vs younger children and older adults



Up to 25-35% of graft losses in young adults have been linked to non-adherence



Increased hospitalizations and health care costs when transition is unstructured

Guidelines and Consensus Statements

- Resources
 - AAP
 - AST
 - NASPGHAN
- Structured, developmentally appropriate, and multidisciplinary transition programs can improve:
 - Adherence
 - Continuity of care
 - Long term graft and survival



Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home

Patience H. White, MD, MA, FAAP, FACP, M. Carl Cooley, MD, FAAP, TRANSITIONS CLINICAL REPORT AUTHORING GROUP, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN COLLEGE OF PHYSICIANS

American Journal of Transplantation 2008: 8: 2230-2242
Why Periodicile Inc.

Meeting Report

Adolescent Transition to Adult Care in Solid Organ

Transplantation: A consensus conference report

L. E. Bell**, S. M. Bartosh*, C. L. Davis*,
F. Dobbels*, A. Al-Uzri*, D. Lotstein*, J. Reiss*,
V. R. Dhamidharka* on behalf of the conference attendees

Original article

Building consensus on transition of transplant patients from paediatric to adult healthcare

Nicholas Webb, ¹ Paul Harden, ² Clive Lewis, ³ Sarah Tizzard, ⁴ Grainne Walsh, ⁵ Jo Wray, ⁶ Alan Watson ⁷

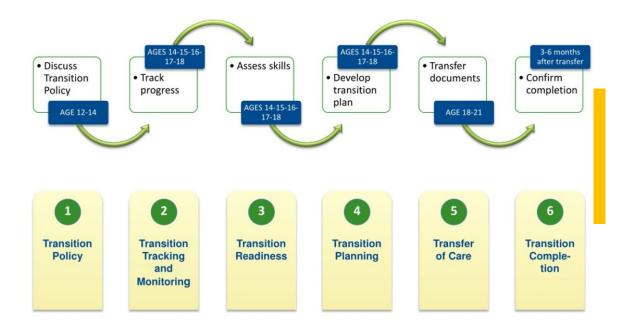
SOCIETAL PAPER: HEPATOLOGY



Health Care Transition for Adolescents and Young Adults With Pediatric-Onset Liver Disease and Transplantation: A Position Paper by the North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition

*Jennifer Vittorio, MD, †Beverly Kosmach-Park, DNP, †Lindsay Y. King, MD, MPH, †Ryan Fischer, MD, "Emily M. Fredericks, PhD, †Vicky L. Ng, MD, "Amrita Narang, MD, **Sara Rasmussen, MD, and ††John Bucuvalas, MD

Six Core Elements of Transition



American Academy of Pediatrics

Six Core Elements framework to guide providers in building adolescents' ability to manage their own medical needs



Children's Wisconsin Resources



Children's Hospital and Health System Patient Care Policy and Procedure

This policy applies to the following entity(s):

Children's Hospital and Health System

SUBJECT: Transition Planning for Youth with Special Health Care Needs (YSHCN) to Adult Health Care Setting

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Transition Letter

Dear {Parents/Patient}

It's time to talk transition! We are writing to inform you about our transition planning process, which will help you build skills and confidence so you can be ready to care for your transplant as an adult. Moving into adulthood can be both exciting and challenging.

At our center, preparation for transition begins for patients who are at least 12 years old and are at least one year post transplant. Starting early allows time to create a transition plan with your team which will help {NAME} become more independent throughout the next few years. This plan will be tailored to meet {NAME's} developmental needs. Our team will use various tools, such as surveys and checklists to better assess these needs

process. You can expect to meet with various members of the multidisciplinary team including the Provider, Social Worker, Dietician, Pharmacist, Psychologist, and Transplant Coordinators. We have enclosed a survey for your review. We will ask you to



Starting the Education Process



Six Core Elements framework recommends beginning at age 12



Some of the first steps focus on laying out the plan

What information do we want patient to learn?

What skills do we want them to develop?



Getting buy-in for step-wise vs immediate approach

Developmental context is important

Education Framework

Domain	Early Adolescence (12-14 years)	Middle Adolescence (14-16 years)	Late Adolescence (16-18 years)
Personal Health Knowledge	 Date of transplant Living vs. deceased donor Medical condition that led to transplant 	 Names of key lab tests Target ranges of labs Reasons for drawing labs 	 History of biopsies and rejection episodes Treatments approaches for rejection episodes
Adherence and Medication Knowledge	 Names of medications Reason for taking medications What strategies caregivers use to support adherence 	 Medication dosages Medication side effects Strategies patient/parent use together to support adherence 	 Name of pharmacy/delivery methods for medications Adherence strategies patient can use independently
Navigating Health Care System	 Names of care team members Roles of care team members 	 Available methods for contacting care team Answering common questions from medical team in clinic 	 Accessing medical records Strategies for scheduling appointments/labs Health insurance information
Health Communication	 How to give brief summary of medical condition/transplant Emergency contact name and phone number 	How to share medical information with peers in event of emergency	Disclosure of medical conditions to schools/employers

Personalizing the Plan



Education about health care needs builds on foundational concepts

- Knowing what "rejection" means builds motivation for learning about personal history of rejection
- Confidence in one's own understanding of their health makes it easier to share with others

Patients will be ready for advanced topics and discussions at different times

Age guidance should be viewed as just that – guidance

Avoid assumptions

More time post transplant may not mean increased knowledge

Transition Documentation



	Office Visit from 9/16/2024 in Main Campus Live				
	9/16/2024				
Search (Alt+Comma)	1000 ▼				
Service Area					
Service area completing assessment	Liver Transplant				
Provider completing assessment	Janetie:				
Learner	Patient; Parent/Guardian				
Health Care-Medical Management					
Able to describe medical condition/disability	Patient needs help; Caregiver does now				
Identifies symptoms caused by condition	Patient received information; Caregiver do				
Recognizes how illness impacts daily life	Patient does now				
Knows how to access information about medical condition	Patient needs help; Caregiver does now				
Manages medical condition independently at home	Patient needs help; Caregiver does now				
Schedules and keeps track of medical appointments	Caregiver does now				
Has list of health care providers & phone numbers	Caregiver does now				
Knows how to access medical records	Caregiver does now				
Initiates call to provider to report problems or give status	Caregiver does now				
Knows emergency contacts and carries phone numbers	Caregiver does now				
Follows provider Plan of Care	Patient does now				
Has copy of clinical summary	Caregiver received information				
Understands nutrition basics	Patient does now				
Understands dangers of tobacco, alcohol, drug use	Caregiver does now				
Understands sexuality, pregnancy and birth control	Caregiver does now				
Health Care-Medication Management					
Knowledgeable of name & purpose of medications and \dots	Caregiver does now; Patient needs help				
Independent taking medication	Patient needs help				
Fills prescriptions independently	Patient needs help				
Calls for refills independently	Caregiver does now				

Resources and Tools



Pediatric Transition Portal

July 24, 2019

This guide prepares adolescents and young adults (AYAs) and parents/guardians for a successful transition to adult care.

Type: Patient Resources, Pediatric COP: Pediatric

- American Society of Transplantation
 - Transition Portal
 - Medical summary template
 - Education plans by age
- Standardized measures
 - Transition Readiness Assessment Questionnaire (TRAQ)
- Technology
 - Telehealth
 - Medisafe app





		No, I do not know	No, but I want to learn	No, but I am learning to do this	Yes, I have started doing this	Yes, I always do this when I need to
Ma	naging Medications	how	Icaili	to do tilis	uonig uns	Heed to
1.	Do you fill a prescription if you need to?					
2	Do you know what to do if you are having a bad reaction					
۷.	to your medications?					
3.	Do you take medications correctly and on your own?					
4.	Do you reorder medications before they run out?					
Αp	pointment Keeping					
5.	Do you call the doctor's office to make an appointment?					
6.	Do you follow-up on any referral for tests, check-ups or					
	labs?					
7.	Do you arrange for your ride to medical appointments?					
8.	Do you call the doctor about unusual changes in your					
	health (For example: Allergic reactions)?					
9.	Do you apply for health insurance if you lose your current coverage?					
10.	Do you know what your health insurance covers?					
11.	Do you manage your money & budget household					
	expenses (For example: use checking/debit card)?					
	cking Health Issues					
12.	Do you fill out the medical history form, including a list of your allergies?					
13.	Do you keep a calendar or list of medical and other appointments?					
14.	Do you make a list of questions before the doctor's visit?					
15.	Do you get financial help with school or work?					
Tal	king with Providers					
16.	Do you tell the doctor or nurse what you are feeling?					
17.	Do you answer questions that are asked by the doctor,					
	nurse, or clinic staff?					
	naging Daily Activities					
18.	Do you help plan or prepare meals/food?					
19.	Do you keep home/room clean or clean-up after meals?					
20	Do you use neighborhood stores and services (For					
	example: Grocery stores and pharmacy stores)?				1	

Strategies for Success

Structured transition programs

• Education, readiness assessments, gradual responsibility shift

Use of transition readiness tools

- TRAQ
- Medication specific sections

Multidisciplinary support is critical

Nursing, psychology, social work, pharmacy

Technology shows promise in improving adherence

• Apps, text reminders, telehealth check-ins

Family involvement is key

• Gradual shift rather than abrupt withdrawal of parental support

How can a pharmacist help?



Medication Adherence in Adolescents

- Several studies have suggested that medication adherence remains a challenge for adolescents
- Should be a core component that is assessed and reviewed in the transition period, given high risk of unexpected graft loss
- Nguyen C. & colleagues surveyed 32 adolescents and young adults (AYA) complete

Medication Adherence in Adolescents

Themes	Illustrative quotes				
Challenges expressed by AYAs					
Difficulty remembering to take medications on time	"It's easier in the school year because you are getting up early but during the summer, it's kind of more relaxed and it can be a little bit more difficult."—22 years old "I have to take my medications four times a day. When I am on my own I have a hard time remembering, so my mom reminds me to do it."—14 years old "If I don't get up and take them right away, then I'll say to myself that I will remember to take them when I get up,				
	but then I forget and I do other things."—15 years old "I think as you get older, you kind of get more busy with different school things so I think it can be a problem to take them at night."—24 years old				
Learning the steps required for medication management	"To begin with, [my coordinator] helped me learn my pills by color, by name, by dose and when they are due. I can tell I'm getting better at remembering these details which makes me feel good."—12 years old "I'm going to want my parents there to help with everything because I have problems that prevent me I have issues remembering or just saying stuff normallyI have a hard time being social because I have anxiety and stuff like autism and stuff that makes it hard for me to be able to do it on my own now."—22 years old "Obviously, I know my dad is not going to let me forget to take my meds, so sometimes I just wait for him to remind me."—17 years old "You have to decide to either take your meds or you don't you need to know it's your responsibility for life."—24 years old				



Role of a Pharmacist

- Huntsman et al studied 27 pediatric heart transplant patients transitioning to an adult clinic
- Transplant pharmacists documented medication list errors in 19 patients
- All 19 patients (100%) had med list errors identified and corrected by pharmacists
- Underscored need for accurate medication history upon transition to adult clinic and potential role for a pharmacist

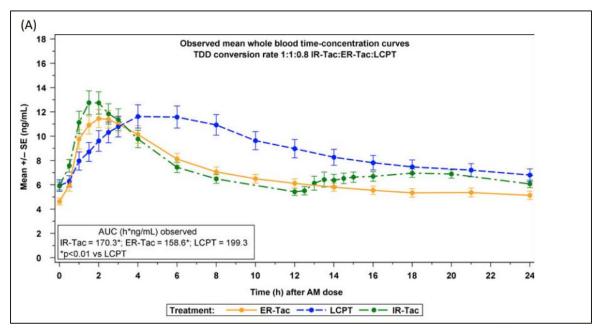
Role of a Pharmacist

- Prestidge E. & colleagues, who successfully implemented a transition clinic, incorporated pharmacist-based care
 - Pill box teaching
 - Develop medication alarms/reminders
 - Link medication administration to daily routine
 - Assist in simplifying medication regimen
 - Review doses, timing, drug and food interactions, adverse events, and indications
 - Provide instructions for missed or late doses and medication refills
 - Assess patient adherence



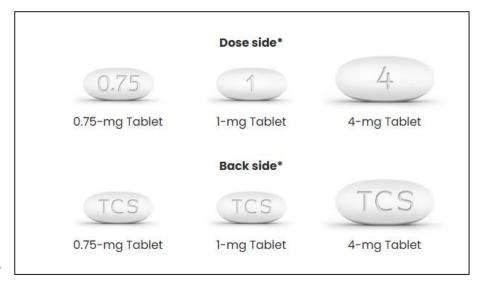
Envarsus XR

- Extended-release formulation of tacrolimus, taken once-daily
- Shown to improve neurotoxicity and adherence rates



Envarsus XR Considerations

- Strengths: 0.75 mg, 1 mg, 4 mg tablets
- Can NOT crush; no liquid or IV formulation
- Conversion from IR:
 - 80% of total daily dose of IR
 - Dose Converter |
 ENVARSUS XR® (tacrolimus extended-release)





Envarsus XR Considerations



ENVARSUS XR 30-Day Free Trial Card*,†

Patients new to ENVARSUS XR may receive a one time per life time free trial.



Bridge Program*

The <u>Bridge Program</u> will provide ENVARSUS XR at no cost to eligible patients who are experiencing a temporary delay in coverage.



Pay as little as \$0 for ENVARSUS XR*,‡

If your patient has commercial insurance, they may be eligible for our \$0 Co-pay Card.



Patient Assistance Program (PAP)*

Veloxis has a patient assistance program to provide ENVARSUS XR at no cost to eligible patients who meet certain criteria.



Conclusions

- Periods of transition from pediatric to adult care are associated with high rates of non-adherence and subsequent graft failure
- Potential barriers include developmental, psychosocial, and financial concerns, in addition to hindrance from caregivers and providers
- In addition to various other strategies for a successful transition, utilization of a transition clinic and transition coordinator have proven to be beneficial
- In light of higher rates of graft loss during this time period, pharmacists can play a core role in reinforcing medication understanding and adherence



Contraception and solid organ transplant

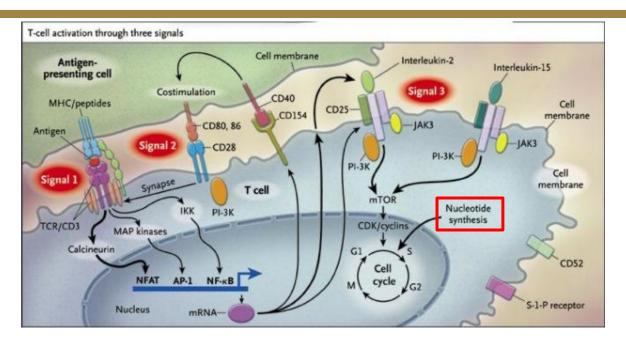


Fertility in solid organ transplant recipients

- Male patients: recovery of hypogonadism by ~ 12 months post transplant
- Female patients: return to fertility can happen as early as 2 months post-transplant in those of childbearing age
- Pregnancy is possible but risky
- Increased risk for preeclampsia, hypertension, graft rejection or failure across all organ groups



Mycophenolate mofetil (MMF)



Inhibitor of inosine monophosphate dehydrogenase (IMPDH),
 which inhibits de novo guanosine

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- Blocks purine synthesis
- T and B lymphocytes are dependent on this pathway for proliferation VANDERBILT >>

MMF and fatherhood

Objective	Compare outcomes of men exposed to MMF or not at the time of conception
Study population	155 men exposed to MMF, 195 men not exposed to MMF at time of conception
Average exposure to MMF	1.42 ± 0.3 g/day
Outcomes	No difference in mean gestational age, malformations, neural tube defects, need for cesarian section, or any other outcomes
Conclusion	MMF is safe for men attempting to conceive a child



MMF and pregnancy

Parameter	General population	Transplant recipients not on MMF	Transplant recipients on MMF
Birth defects	3 – 5%	4 – 6%	~14%
Early miscarriage	8 – 20%	~13- 22%	28 – 64%

 Congenital malformations: microtia-external auditory canal atresia, facial clefts, cardiac, skeletal, eye, tracheoesophageal, and facial anomalies



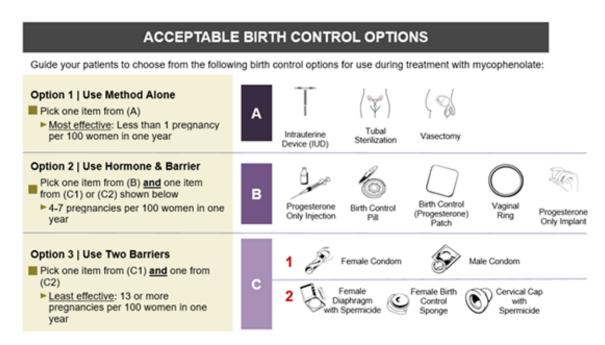
Mycophenolate Risk Evaluation and Mitigation Strategy (REMS)

- Step 1: Document education on mycophenolate risks
 - Higher risk of miscarriage in first 3 months
 - Higher risk for birth defects
 - Congenital Malformations: external ear, cleft lip, cleft palate
 - Anomalies of distal limbs, heart, esophagus, kidney, nervous system



Mycophenolate Risk Evaluation and Mitigation Strategy (REMS)

- Step 2: Educate females of reproductive potential
 - Acceptable contraception must be used during entire treatment and for 6 weeks after the cessation of mycophenolate





Mycophenolate Risk Evaluation and Mitigation Strategy (REMS)

- Step 3: Check pregnancy status
 - Immediately before starting mycophenolate and at follow up visits
- Step 4: Report any pregnancies to mycophenolate pregnancy registry



Mycophenolate and oral contraceptives (OCs)

- Mycophenolic acid (MPA) undergoes enterohepatic circulation
- Secondary peak at 6 to 12 hours after dose
- Active glucuronide metabolites are excreted into bile by multidrug resistance related protein 2 (MRP2)
- Undergoes deglucaronidation back to MPA by colonic bacteria



Mycophenolate and OCs

- Estrogen competes for transporters in gut to be taken up for enterohepatic recycling
- Less enterohepatic recycling → more excreted in first pass metabolism
- Decreased serum levels of estrogen → decreased effectiveness of contraception



Summary and recommendations

- Mycophenolate is not associated with birth defects in children of males on this medication
- Mycophenolate exposure is associated with early miscarriage and birth defects in fetuses
- Education on the risks of taking mycophenolate and proper contraception during use of this drug is essential



Family planning in solid organ transplant recipients

- Studies abroad reported rates of unplanned pregnancy in solid organ transplant recipients of 48.5% - 92.9%
- Study from 2013 had 71% planned pregnancy rate
- Increased fertility after transplant in women of childbearing age highlights need for education from healthcare team about contraceptive options



Contraception and fertility awareness among women with solid organ transplants

Objective

 Assess awareness regarding post-transplantation fertility and determine what contraceptive methods were recommended post transplant

Design

- Telephone of patients at Nebraska Medical Center
- Women aged 19 49
- Telephone survey with 19 multiple choice questions about reproductive health

Contraception and fertility awareness among women with solid organ transplants

Population

- 183 women responded to survey
- 40% kidney transplant, 32% liver transplant, 28% other transplants
- Average age at transplant was 29 years
- Average time from transplant to survey was 10 years

Results

- 44% of women were aware they could become pregnant post transplant
- After transplant, 37% of women were counseled on contraception,
 52% of these women had method recommended by provider



Contraception and fertility awareness among women with solid organ transplants

Results (cont.)

- 62% of patients aged 15-44 were using contraception at time of survey
- Female sterilization was utilized by 27% of patients, 28% of patients utilized oral contraceptives

Conclusions and study implications

- Overall, women poorly informed of contraceptive options and fertility post transplant
- Pharmacists can have a role in discussion of safe options and fertility awareness



Contraception in solid organ transplantation

- American Society Of Transplantation (AST) guidelines (2005) acknowledge barrier method as most widely accepted form of contraception
- International Society of Heart and Lung Transplant (2023) states barrier methods alone are not adequate, hormonal oral contraceptives, injection and intrauterine devices also carry risks
- CDC guidelines (2024) recommend using the highest effective birth control for those at increased risk for adverse health events as a result of pregnancy
 - Includes 2 years within solid organ transplant operation



CDC guidance – CKD with current nephrotic syndrome, hemodialysis and peritoneal dialysis

No	Benefit >	Risk >	Avoid
Restriction	Risk	Benefit	
• Cu-IUD*	LNG-IUDImplantPOP	• DMPA	DRSP POP with hyper- kalemiaCOC

^{*}For patients on peritoneal dialysis, Cu-IUD falls in the (B>R) category

COC = combined oral contraceptive; CKD = chronic kidney disease; CuIUD = copper intrauterine device; DMPA = depot medroxyprogesterone acetate;

DRSP = drospirenone; IUD = intrauterine device; LNG-IUD = levonorgestrel
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CDC guidance – Solid organ transplant with no graft failure

No	Benefit >	Risk >	Avoid
Restriction	Risk	Benefit	
Cu-IUDLNG-IUD	ImplantDMPAPOPCOC	 DMPA (with risk factors for or history of fracture) 	 COC (with Budd- Chiari syndrom e)



CDC guidance – Solid organ transplant with graft failure

No	Benefit >	Risk >	Avoid
Restriction	Risk	Benefit	
Cu-IUD(C)LNG-IUD(C)	 Cu-IUD (I)LNG-IUD(I)ImplantDMPAPOP 	 DMPA (with risk factors for or history of fracture) 	• COC

CDC guidance – Solid organ transplant & emergency contraception

No Restriction	n Benefit > Risk
• Cu-IUD	 Cu-IUD (if graft
• LNG	failure present)
• UPA	
• COC	

Cu-IUD = copper intrauterine device

LNG = levonorgestrel (Plan B)

UPA = ulipristal acetate (Ella)

COC = combined oral contraceptive



International Society of Heart and Lung Transplantation (ISHLT) guidance

- Half of pregnancies in heart and lung transplant patients are unplanned
- Education should begin during pre-transplant evaluation period if applicable
- Disturbances to fertility resolve in 2-6 months following transplant
- Effective contraception should be recommended immediately

International Society of Heart and Lung Transplantation (ISHLT) guidance

"Preconception counseling for all individuals of childbearing age encompasses pregnancy intention, contraception, timing of conception after transplant, maternal risks including those unique to transplant recipients, fetal risks, and psychosocial support for optimal shared decision-making."



ISHLT guidance

Method	Consensus	Alone or with barrier method	Notes
IUD	Preferred	Alone	Highly effective, lack of drug interactions
DMPA	Not recommended >2 years	Use with barrier method	Decreased bone density, delayed return to fertility, weight gain
Implant	Acceptable	Use with barrier method	Rapid return to fertility



ISHLT guidance

Method	Consensus	Alone or with barrier method	Notes
POPs	Not recommended given diminished efficacy with non-adherence	Use with another method	Short ½ life, less efficacious if taken >3 hours past dosing time
COCs	Not recommended as sole method	Use with barrier method	CI: hyper-coagulable states, history of stroke or thrombosis, liver disease Avoid: transplant related CAD or HTN Inhibits CYP3A4 Less efficacious

CI: contraindicated

CAD= coronary artery disease

HTN= hypertension

J Heart Lung Transplant. 2023 Mar;42(3):e1-e42



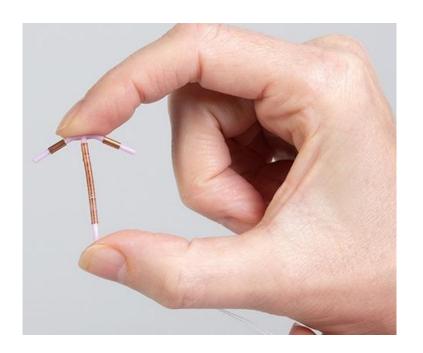
Copper Intrauterine Devices (Cu-IUD)

- Copper ions are spermatotoxic, inhibit motility of sperm
- Alternative mechanism: the copper stimulates an inflammatory reaction in the uterus

Benefits

- No hormones
- Highly effective
- Lasts 10 years

- Theoretical infection risk
- Theoretically less effective in immunosuppressed
- May be considered more invasive





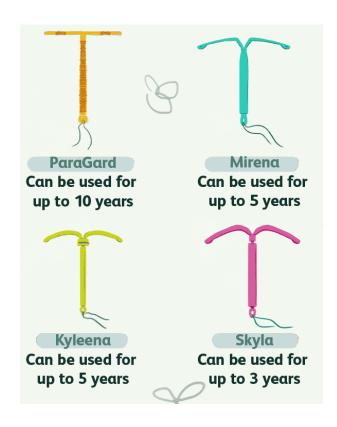
Levonorgestrel Intrauterine Devices (LNG-IUD)

 Mechanism: local effects of progestin cause thickened cervical mucous, glandular atrophy, slowed tubal motility

Benefits

- Highly effective
- Last 3 5 years
- No utilization of immune response
- Local effect, less systemic absorption of hormones

- Theoretical infection risk
- May be considered more invasive





LNG-IUD

Study	Methods	Results
Ramhendar et al	11 kidney transplant recipients with LNG-IUD Median duration: 38 months	No unplanned pregnancyNo documented infection
Huguelet et al	2 kidney, 2 cardiac, 1 liver, 1 small bowel recipient with LNG-IUD Duration range: 1 – 32 months	 No unplanned pregnancy No documented infection
Paulen et al	21 kidney, 2 liver transplant recipients with LNG-IUD Median duration: 49.3 months	 No unplanned pregnancy No documented infection



Implant: Etonorgestrel (Nexplanon)

 Progestin within flexible implant placed in arm

Benefits

- Highly effective
- Lasts 3 years

- Theoretical infection risk
- Menstrual disturbances reported
- May be considered more invasive





Implant: Etonorgestrel (Nexplanon)

Study	Methods	Results
Lew et al	Outcomes: pregnancy pattern, post-transplant infections	 No insertion site infections
Case control study	Groups: Etonorgestrel users (n=24), no hormonal contraceptives (n=24)	 No difference in graft rejection, failure, or infection of any kind 3 discontinuations due to side effects



Depot medroxyprogesterone acetate (DMPA): injection

 Progesterone delivered by intramuscular injection

Benefits

- Lasts 12 weeks
- More effective than the pill

- Decline in bone mineral density
- Menstrual disturbances
- Weight gain
- Pain with injections





Progestin only pills (POP)

Oral pill, progesterone only

Benefits

- Non-invasive
- No estrogen content

- Lower efficacy
- Must take within 3 hour time window
- Extensively metabolized in liver





Combined oral contraceptives

 Oral pill containing estrogen and progesterone

Benefits

- Non-invasive
- More flexibility with schedule

- Lower efficacy than long acting methods (9% failure rate)
- Metabolized through CYP 3A4, affects immunosuppression levels
- MMF may lower efficacy
- Risk of thromboembolism



Summary and recommendations

- The transition from pediatrics to adults is a high risk time period for both medication non-adherence and other risky behaviors
- When possible, a pharmacist should be involved in education of these patients and should be involved to identify areas for medication regimen optimization
- A process should be identified to ensure patients of appropriate age are educated about contraception



Questions?

