	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
RECORDS THAT PERTAIN TO ALL PHARMACY SETTINGS					
Clinical governance	Competency/training records	Yes	Reference	Clinical training: until 75th birthday or duration of employment plus 6 yrs whichever is longer. Statuatory/mandatory training: 10yrs after training completed Other training: 6 yrs after training completed.	Records Management Code of Practice for Health & Social Care, Jul 2016
	Clinical audit	Yes	Reference	5 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
	External quality control records	Yes	Audit	12 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
	Patient surveys	Yes	Audit	5 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
	Patient complaints	Yes	Audit	10 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016 Where a legal action has commenced, keep as advised by legal representative.
Clinical interventions	Minor clinical interventions	Yes	Audit	2 yrs	Best practice. Two part paper form recommended, original to be added to the patient record, duplicate kept for 2 yrs. Entries made on an electronic database should be reviewed after 2 yrs, if no longer needed, destroy or permanently delete record.
	Significant clinical interventions	Yes	Audit	For 10 yrs after the death of the patient	Clinically significant interventions should be recorded directly in the patients notes/ PMR.
Controlled drugs (CD)	CD register	Yes	Legal	2 yrs from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 yrs	Misuse of Drugs Regulations 2001 A guide to good practice in the management of controlled drugs in primary care (England) v3.1, updated 1 Oct 2010. Safer management of controlled drugs: a guide to good practice in secondary care (England). Dept of Health, October 2007. Electronic CD register - see note 2. In Secure Environments Schedule 3 CDs are also recorded in CD registers (PSI IDTS 2010/45)
	Requisitions, orders, order books, delivery note or other record of receipt	No	Legal	2 yrs or 2 years from date of last entry for record books.	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 yrs. Includes hospice requisitions, prison services & others not sent to NHSBSA. See note 3.
	Extemporaneous CD preparation worksheets	Yes	GMP	13 yrs	See note 3.
	Validation of equipment & maintenance logs	Yes	GMP	For life of equipment	Best practice.
	Cleaning logs	Yes	Reference	1 yr	Best practice.

Disclaimer: Every effort has been made to ensure all required records have been listed, if in doubt, pharmacists are advised to read the relevant legislation and to seek appropriate advice.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
Controlled drugs (CD) cont.	CD transportation by road vehicle	Yes	Audit	Driver ID: 3 mths. Recipients signature: 6 mths in original form; then up to 18 mths in reproducible form. Orders, signed orders, requisitions, private prescriptions: 2 yrs.	Guidance for the safe custody of controlled drugs and drug precursors in transit, Home Office Sept 2013
	Fridge temperature	Yes	GMP/GDP	1 yr or longer for sites holding a Wholesale Dealers Licence	Refrigerator records to be kept for the life of any product stored therein – particularly vaccines. For sites subject to GDP inspection (licensed wholesale) records should be kept for 5 years as with other GDP records. SOPs detailing actions required in the event of fridge failure should also be available.
Patient safety incidents	Dispensing error records/incidents & associated stats	Yes	Audit	1 yr plus current	Recommendations only apply to paper records, entries made on electronic databases should be kept permanently.
	Dispensing incidents – serious resulting in disability or death	Yes	Legal	20 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
Recalls/drug alerts	Recall documentation	Yes	Audit	5 yrs	Recommendations from the Good Distribution Guide - especially for those with wholesale dealers licence.
Responsible pharmacist	Responsible pharmacist records/log book	Yes	Legal	At least 5 yrs	Can be in hard copy or electronic. Medicines (pharmacies/responsible pharmacist) Regulations 2008 (SI 2008/2789).
Superseded documents	Superceded SOPs	No	Reference	15 yrs	Best practice.
	Superceded Patient Group Directions (PGDs)	No	Reference	8 yrs for adult and 25 yrs for child (0-18 yrs) or for 8 yrs after a child's death	Best practice.
Stock handling and transfer	Picking tickets/delivery notes	Yes	Uncertain	3 months	A "reasonable" period of time - for verification of order only.
	Old order books	No	Audit	2 yrs	Current financial yr plus 1.
	Invoices	Yes	Legal	6 complete tax yrs	Limitation Act 1980. See note 4.
	Wholesale dealing records	Yes	GDP	5 yrs	EU Guide on Good Distribution Practice (part of the Orange Guide).
Waste medicines	Destruction of patients' own drugs (excluding controlled drugs)	Yes	Audit	6 months	Revised Duthie Report (2005) states that patient's own drugs are the property of the patient and should only be destroyed with their permission. If medicines are removed from a patient's home during a domiciliary visit, record what is destroyed.
	Waste - Non-hazardous Transfer notes	Yes	Legal	2 yrs	Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012.
	Waste - hazardous Consignment notes	Yes	Legal	3 yrs	Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012.

HOSPITAL PHARMACY SPECIFIC RECORDS (also applicable to Secure Environments - see Note 8)

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
Clinical Trial	IMP batch production records	Yes	GMP/GCP	5 yrs after end of the trial	Article 9 of Directive 2003/94/EC.
	Protocols	Yes	Reference	5 yrs after end of the trial	See note 1.
	Dispensing records	Yes	Reference	5 yrs after end of the trial	-
	Destruction records	Yes	GMP	5 yrs after end of the trial	The sponsor of the trial is responsible for the destruction of unused and/or returned trial material. Therefore any destruction must be authorized in writing and a dated destruction certificate supplied to the sponsor.
	Preparation or dispensing of ATMPs	Yes	Reference	30 yrs	ATMP = Advanced Therapeutic Medicinal Products.
	CD clinical trials information	Yes	GMP	5 yrs	This may be longer for some trials.
	Clinical drug trials or other studies outwith the Clinical Trials Directive	Yes	GCP / Against future claims	5 yrs after end of the trial	For example - metabolic studies, nutritional studies. Article 17 of Directive 2005/28/EC for Clinical trials, otherwise good practice.
Controlled Drugs	CD ward orders or requisitions	No	Legal	2 yrs	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 yrs. Keep in original paper form or computerised form.
	Copy of signature for CD ward order or requisition	Yes	Validation	Duration of employment	Copy of signature of each authorized signatory should be available in the pharmacy department. Safer Management of Controlled Drugs – A guide to good practice in secondary care (England), Oct 2007.
	CD record book (ward/theatre based)	Yes	Audit	2 yrs from date of last entry but if it contains records of destruction of CDs (including patient returns and out of date stock) then keep for 7 yrs	Safer Management of Controlled Drugs – A guide to good practice in secondary care (England), Oct 2007. See note 2.
	Aseptic CD worksheets - adult paediatric	Yes Yes	GMP GMP	13 yrs 26 yrs	See note 3.
	CD clinical trials information	Yes	GMP	5 yrs	This may be longer for some trials.
	Destruction of patients' own CDs	Yes	Audit	7 yrs	Revised Duthie Report (2005) states that patient's own drugs are the property of the patient and should only be destroyed with the patient's permission.
	CD prescriptions (Both inpatient and outpatient)	Yes	Legal	2 yrs	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 yrs. (Secure Environments see Note 9)
Medicines Information	Question asked, information search & answer	Yes	Reference and audit	8 yrs (25 yrs for child, obstetrics and mental health enquiries)	Recommendations apply to previous paper based enquiry forms. [UKMI National Standard for MI services, March 2009]. Electronic enquiry database (MIDatabank) should be kept permanently.
Miscellaneous	Doctors/nurses signatures	Yes	Reference	Duration of contract + 1 yr	Destroy 1 yr after termination of employment (not referenced, best practice).
	Self administration records	No	Reference	Not required	Will be kept in nursing notes/main medical record.
	Superceded IV drug administration monographs	No	Reference	10 yrs	-
	MR documentation	Yes	Audit	2 yrs	See note 5.

Disclaimer: Every effort has been made to ensure all required records have been listed, if in doubt, pharmacists are advised to read the relevant legislation and to seek appropriate advice.

	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
Miscellaneous cont.	Drug & Therapeutics Committee agendas, letters, minutes, drug submissions etc.	No	Reference	20 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
Prescriptions	To take out (TTO) prescriptions	No	Audit	2 yrs	EPR will eventually hold all details - duplication of record held in notes, see note 5.
	Out-patient prescriptions	No	Audit	2 yrs	EPR will eventually hold all details - duplication of record held in notes, see note 5.
	Private prescriptions	Yes	Audit	2 yrs	According to RPSGB ethics guide this is the minimum requirement. (Secure Environments see Note 8)
	Unlicensed medicines dispensing record	Yes	Legal	5 yrs	Requirement of Guidance Note 14. Permanent record of batch details kept.
	Parenteral nutrition (PN)	No	Audit	2 yrs	Original valid prescription should be kept in patient's notes.
	Chemotherapy prescriptions	No	Reference	2 yrs after last treatment	EPR will eventually hold all details - duplication of record held in notes.
	Clinical drugs trials or other studies outwith the Clinical Trials Directive	Yes	GCP / Against future claims	5 yrs after end of the trial	For example - metabolic studies, nutritional studies. Article 17 of Directive 2005/28/EC for Clinical trials, otherwise good practice.
	Immunoglobulins/blood products	Yes	Reference	30 yrs	To allow full traceability of all blood products use.
	Pads of FP10s usage & issue sheets	Yes	Legal	5 yrs	-
Purchase Orders	Order & delivery notes	No	Audit/GDP	2 yrs or 5yrs	Current financial yr plus 1. See note 4. Wholesaler Dealers EU Guide on Good Distribution Practice requires retention of all records for 5yrs.
	Ward stock order sheets	Yes	Audit	2 yrs	Current financial yr plus 1.
	Ward pharmacy requests	No	Uncertain	1 yr	Record of what was requested by ward pharmacist - unlikely benefit after 12 mths.
	Ad hoc forms (e.g. dispensing request forms to stores)	No	Uncertain	3 months	Reasonable period and current practice.
Stock Control	Stock check lists	Yes	Audit	1 yr plus current	As in HSC 1999/053.
Technical services	Any Quality Control (QC) documentation including certificates of analysis	Yes	GMP	5 yrs or 1 yr after expiry date of batch	Whichever is the longer, (Article 51(3) of Directive 2001/83).
	Environmental monitoring results	Yes	GMP	1 yr after expiry dates of products	If an electronic record, keep for 10 yrs then review & destroy if no longer needed. Records Management Code of Practice for Health & Social Care, Jul 2016
	Validation/training of operators	Yes	GMP	Duration of employment + 5 yrs after leaving	Keep in personal portfolios.
	Paediatric products worksheets	Yes	GMP	At least 5 yrs	Product liability extends to up to 28 yrs. See note 6.
	Chemo/aseptic worksheets	Yes	GMP	5 yrs	Product liability extends this to 11 yrs after expiry.
	PN worksheets	No	GMP	5 yrs	Product liability extends this to 11 yrs after expiry.
	Resuscitation box worksheet	Yes	GMP	1 yr after expiry of longest dated item	If sold or supplied across a legal boundary 5 yrs or 1 yr after expiry date of batch as per GMP.
	Batch production records	Yes	GMP	5 yrs	Product liability extends this to 11 yrs after expiry.

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	Record	Unique record	Reason for keeping	Recommended minimum period	Derivation of recommendation and comments
Technical services cont.	Extemporaneous dispensing records	Yes	Product liability	5 yrs	Product liability extends this to 11 yrs after expiry.
	Raw material request; packaging and control forms	Yes	GMP	At least 5 yrs	Part of batch record, so product liability issues apply (extends to 11 yrs after expiry).
	Medical gas pipeline systems – High hazard permits to work	Yes	Reference	For the lifetime of the pipeline system	HTM02-01, Part B, Chapter 6 (http://www.bcga.co.uk/assets/HTM_02-01_Part_B.pdf)
Unlicensed medicines	Any unlicensed medicines (ULM) documentation	Yes	Legal/Against future claims	5 yrs	Not a specific requirement of Guidance note 14, it would be best practice to keep a permanent batch specific record of the assessment of the ULM purchased.
COMMUNITY PHARMACY SPECIFIC RECORDS					
Dispensing	PMR	Yes	Legal	For 10 yrs after the death of the patient	Records Management Code of Practice for Health & Social Care, Jul 2016
	Private prescriptions	Yes	Legal	2 yrs	The Human Medicines Regulations 2012 (regulation 253 (5))
	POM register	No	Legal	2 yrs from last entry	The Human Medicines Regulations 2012 (regulation 253 (5))
	POM-V & POM-VPS records of receipt and supply	Yes	Legal	At least 5 yrs	Veterinary medicines regulations 2009 (SI 2297). Must keep all documents relating to the transaction. Specific requirements for what information must be included.
EPS2	Patient pharmacy nomination	Yes	Audit	6 mths after the last prescription the collected	Best practice. This also applies to patient authorisations for managed repeat systems.
Specials and unlicensed medicines	Extemporaneously prepared on the premises with internal quality control.	Yes	Legal	5 yrs	The Human Medicines Regulations 2012 (regulation 170). Product liability extends this to 11 yrs after expiry for adults and up to 28 yrs for children. See note 4.
	Extemporaneously prepared by another pharmacy/company with external quality control	No	Legal	5 yrs	The Human Medicines Regulations 2012 (regulation 170). Should have the certificate of conformity including the source of the product; to whom, and the date on which the product was sold or supplied; the prescriber's details; the quantity of each sale or supply; the batch number of the product; details of any adverse reactions to the product sold or supplied. See note 4.
	Unlicensed imports	No	Legal	5 yrs	
DDA / Equality Act	Record of assessment and outcome of patients needs in respect of medicines	Yes	Reference	Minimum 1 yr	Best practice Assessment should be repeated if patient circumstances change.
Public Health Campaigns	Evidence of participation in local public health campaigns	Yes	Reference	2 yrs	Where requested by the commissioner to do so, records should be kept to evidence compliance with Terms of service of Pharmacists – Schedule 4, part 2, para 18 (b) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
Advanced services	MUR records	Yes	Legal	2 yrs	Records can be kept electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep copies of the MUR consultation record for at least two years after the date on which the consultation to which the record relates is carried out (Direction 5(1)(l)).

Disclaimer: Every effort has been made to ensure all required records have been listed, if in doubt, pharmacists are advised to read the relevant legislation and to seek appropriate advice.

	Record	Unique record	Reason for keeping	Recommended minimum period	Comments
Advanced services cont.	New medicine service forms	Yes	Legal	2 yrs	Records can be kept electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep copies of the NMS consultation records for at least two years after the date on which the service intervention is completed or discontinued (Direction 7(1)(n)).
	Stoma appliance customisation	Yes	Legal	12 months	Records can be kept ielectronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep records of each stoma customisation for at least 12 months or such longer period as the commissioner may reasonably require (Direction 10(2)(d)).
	Appliance use review	Yes	Legal	12 months	Records can be kept in electronically or in hard copy. The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 require pharmacies to keep records of each AUR for at least 12 months or such longer period as the commissioner may reasonably require (Direction 12(5)(e)).
Enhanced services, locally commissioned services or private services See Note 7	Sexual Health service forms	Yes	Audit	For adults aged 18 yrs and over: 8 yrs For a child: until the 25th birthday or 26th birthday if the patient was 17 yrs when treatment finished.	Records Management Code of Practice for Health & Social Care, Jul 2016 Clinical Standards Committee, Faculty of Sexual and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists. NB The longest licence period for a contraceptive device is 10 years.
		No	Reference	Where individual patient records are kept by a sexual health team and a shorter minimum period for retaining records may be stated in the service level agreement.	
	Smoking cessation service	Yes	Audit	2 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
	Supply of Smoking cessation therapy e.g. NRT not via FP10 or via PGD	Yes	Audit	2 yrs	Records Management Code of Practice for Health & Social Care, Jul 2016
	Minor ailments service	Yes	Audit	2 yrs	Recommended best practice.
	Immunisation and vaccination records	Yes	Audit	Retain until the patient's 25th birthday or 26th if the person was 17yrs old when treatment finished. All others retain for 8 yrs after end of treatment.	Records Management Code of Practice for Health & Social Care, Jul 2016
	NHS health check	No*	Audit	2 yrs	Best practice [*If the results are forwarded to the patients GP]
	NHS health check	Yes**	Audit	2 yrs	Best practice [**Where results are not forwarded to the GP]
	Substance misuse service forms	Yes	Audit	2 yrs	Recommended best practice

Disclaimer: Every effort has been made to ensure all required records have been listed, if in doubt, pharmacists are advised to read the relevant legislation and to seek appropriate advice.

	Record	Unique record	Reason for keeping	Recommended minimum period	Comments
Invoices and consent forms	All payment claims, invoices and patient consent forms relating to any advanced or enhanced service	Yes	Audit	6 complete tax years	VAT regulations 2005 for invoices. Individual signed consent forms support the invoiced claim. NOTE: Enhanced service consent forms represent consent at the point in time the service is provided and are not proof of ongoing consent.
Other records	Any other records pertaining to individual patient care in community pharmacy, not covered elsewhere in this document.	Yes	Audit	2yrs	Best practice. This recommendation only applies for paper records, it is accepted that, where appropriate, records relating to patient care e.g. self care, signposting, telephone queries should be entered on the PMR, either directly or transferred from paper records. Entries made on the PMR should be kept permanently.

KEY

GMP = good manufacturing practice; GDP = good distribution practice; GCP = good clinical practice; MR = medicines reconciliation; MUR = medicines use review

Where GMP is given as the reason for keeping the record, this would be legally enforceable for all unlicensed medicines and for any manufacturing of medicines under an MHRA licence. Any reason for keeping other than 'legal' can be regarded as best practice.

Note 1	The sponsor of the trial is responsible under current legislation for keeping trial records. All clinical trial records should be retained for a longer (up to 15 years) if required by the applicable regulatory requirement(s) or if needed by the Sponsor as per Annex 1 to Directive 2001/83/EC and GCP requirements CPMP/ICH/135/95.
Note 2	Once electronic CD registers are in widespread use, the Government intends to require anyone required to keep secure copies of a CD register for up to 11 years. (Department of Health. Safer management of CDs: Changes to the record keeping requirements, guidance for England only. Last revised February 2008)
Note 3	Every requisition, order or private prescription on which a CD is supplied must be preserved by the pharmacy department for a minimum of 2 years from the date on which the last delivery under it was made. Although the mandatory period for keeping requisitions is 2 years, health care organizations may wish to store them for longer periods, as cases often come to court at a much later date. Future regulations may increase the period of time for the storage of records. (Department of Health/RPSGB, Safer management of controlled drugs – a guide to good practice in secondary care. (England) Oct 2007)
Note 4	Either delivery notes or invoices should be kept for 11 years as product liability records.
Note 5	Where the electronic system has the capacity to destroy records in line with the retention schedule, and where a metadata stub can remain demonstrating that a record has been destroyed, then the Records Management Code should be followed in the same way for electronic records as for paper records with a log being kept of the records destroyed. If the system does not have this capacity, then once the records have reached the end of their retention periods they should be inaccessible to users of the system and upon decommissioning, the system (along with audit trails) should be retained for the retention period of the last entry related to the schedule. (Records Management Code of Practice for Health & Social Care, Jul 2016)
Note 6	Consumer Protection Act 1987 allows patients to claim up to 10 years after a medicine has been administered (in paediatrics up to 28 years - maturity plus 10 years). If adequate records are available in the patient's notes, the records should only need to be kept for the period stated under the recommendation.
Note 7	For locally negotiated services, if the minimum retention period stated in the contractual arrangement of the service level agreement (SLA) exceeds the recommendations of this document contractors must adhere to the SLA.
Note 8	NHS England directly commissions healthcare in all residential Secure Environments (prisons, Immigration Removal Centres and Secure Training Centres). Prescriptions generated in these settings are therefore NHS prescriptions and not private prescriptions. The expectations for prescriptions and other record retention for these settings are in the main as for hospital settings. A wing or treatment room is considered equivalent to a hospital ward. (NPC 2009 A Guide to Good Practice in the Management of Controlled Drugs in Primary Care). The community pharmacy section of this document is relevant where Advanced services or additional enhanced services are commissioned.
Note 9	In addition to retaining the CD prescription a copy of the current CD prescription (i.e. Schedule 2 and 3) for a patient should be available on patient transfer to another secure setting. To achieve this either a scanned e-copy or a hard copy transferred with the patient is needed. This is essential for enabling continuity of supply on transfer until the prescription is reviewed. (PSI IDTS 2010/45) and Best Practice.

Bibliography

The following publications provide the source for the recommendations –

Records Management Code of Practice for Health & Social Care, Jul 2016
Misuse of Drugs Regulations 2001
A guide to good practice in the management of controlled drugs in primary care (England) v3.1, updated 1 Oct 2010.
Guidance for the safe custody of controlled drugs and drug precursors in transit, Home Office Sept 2013
Safer management of controlled drugs: a guide to good practice in secondary care (England). Dept of Health, October 2007.
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Good Distribution Guide
Medicines (pharmacies/responsible pharmacist) Regulations 2008 (SI 2008/2789).
Limitation Act 1980
EU Guide on Good Distribution Practice (part of the Orange Guide).
Duthie report 2005
Safe management of healthcare waste (version 2.0), Dept of Health & Environment Agency, 2012.
Article 9 of Directive 2003/94/EC.
Article 17 of Directive 2005/28/EC for Clinical trials
Wholesaler Dealers EU Guide on Good Distribution Practice
RSPGB ethics guide
Guidance note 14
HSC 1999/053
Article 51 (3) of Directive 2001/83
HTM02-01, Part B, Chapter 6
The Human Medicines Regulations 2012 (regulation 253 (5))
Veterinary medicines regulations 2009 (SI 2297).
The Human Medicines Regulations 2012 (regulation 170).
Terms of service of Pharmacists – Schedule 4, part 2, para 18 (b) to regulation 11(1)(a)(i) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 Direction 5(1)(l); 7(1)(n); 10(2)(d) and 12(5)(e).
Clinical Standards Committee, Faculty of Sexual and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists.
VAT regulations 2005 for invoices

Prepared by Katie Smith, Director, East Anglia Medicines Information Service on behalf of the East of England Senior Pharmacy Managers Network; with special thanks to Rob Lowe, Quality Assurance Specialist Services, East of England and Northamptonshire; Tim Root, Clinical Governance & Technical Services, NHS England Specialist Pharmacy Service; Denise Farmer, Pharmaceutical Adviser Health and Justice Commissioning, NHS England (Central and East Anglia Area Team); Stacey Golding, Senior Pharmaceutical Adviser (Governance), NHS East and North Herts CCG and Jane Newman, Pharmacy LPN Chair Essex, October 2016.

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